UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS

[REDACTED VERSION]

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I. INTRODUCTION

Plaintiffs move for partial summary judgment, asking the Court to find as a matter of law that each Track 1 Defendant has committed unfair and deceptive acts or practices in violation of Mass. Gen. Law Ch. 93A, § 2 (hereinafter "G.L. Ch. 93A"). Based on the overwhelming weight of evidence detailed in this memorandum, there is no genuine issue of material fact that (i) AWP was the reimbursement benchmark under Medicare Part B, and each Track 1 Defendants consistently recognized that it was; (ii) Defendants AstraZeneca,[1] BMS,[2] GSK,[3] Johnson & Johnson ("J&J"),[4] and Schering-Plough[5] controlled the AWPs that were published for the Part B drugs that are the subject of this litigation (the "Subject Drugs"); and (iii) those AWPs did not reflect averages of real prices in the marketplace, did not include a multitude of discounts that, pursuant to Office of the Inspector General Guidelines (the "OIG Guidelines), should have been included, and indeed, each Track 1 Defendants manipulated and marketed the spreads on their Subject Drugs in order to protect or gain market share. As a result of the fictitious and inflated

[1] "AstraZeneca" is used to refer to AstraZeneca, PLC; Zeneca, Inc.; AstraZeneca Pharmaceuticals L.P.; and AstraZeneca U.S.

[2] "BMS" or the "BMS Group" is used to refer to Bristol-Myers Squibb Co.; Oncology Therapeutics Network Corp. ("OTN"); and Apothecon, Inc. Where appropriate, OTN is sometimes referred to separately.

[3] "GSK" is generally used to refer to GlaxoSmithKline, P.L.C. GSK is the result of a merger between GlaxoWellcome, Inc. ("Glaxo") and SmithKline Beecham Corporation ("SKB"). Where appropriate, "Glaxo" and "SKB" are used to refer to the pre-merger companies.

[4] "J&J" refers to Johnson & Johnson; Centocor, Inc.; Ortho Biotech, Inc. ("OBI"); McNeil-PPC, Inc.; and Janssen Pharmaceutica Products, L.P. Where appropriate, OBI is referenced separately.

[5] The Schering-Plough Group consists of the parent-corporation, Schering-Plough Corporation ("SP"), and its wholly-owned subsidiary, Warrick Pharmaceuticals Corporation ("Warrick"). In this memorandum, "SPW" is generally used where the evidence applies against both parent and subsidiary. Where a distinction needs to be made, "SP" or "Warrick" are referenced separately.

AWPs either reported or republished by the Track 1 Defendants, the Class 1 and 2 Plaintiffs and Class Members substantially overpaid for Subject Drugs.[6]

This course of conduct is both unfair and deceptive under G.L. Ch. 93A as a matter of law. It is unfair because the practice (i) is within the penumbra of common-law, statutory, or other established concept of unfairness; (ii) is immoral, unethical, oppressive or unscrupulous; and (iii) causes substantial injury to consumers, competitors or other business people. *See infra* at Part IV.A. The course of conduct is also deceptive in that it has an undeniable capacity to deceive. *See infra* at Part IV.B.[7]

Under these circumstances, partial summary judgment on these issues should be granted without further delay and in favor of the Class 1 and 2 Plaintiffs and the members of Classes 1 and 2.

II. SUMMARY JUDGMENT STANDARDS

Summary judgment is appropriate when the pleadings and evidence demonstrate that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36 (1st Cir. 1995) (citing Fed. R. Civ. P. 56(c)). To succeed, the moving party must show that there is an absence of

[6] Class 1 is generally defined to include "[a]ll natural persons nationwide who made, or who incurred an obligation enforceable at the time of judgment to make, a co-payment based on AWP for a Medicare Part B covered Subject Drug . . . that was manufactured by [one of the Track 1 Defendants]." January 30, 2006, Consolidated Order Re: Motion for Class Certification (the "Final Class Order") at 1-2, ¶ 1. Class 2 is generally defined to include "[a]ll Third-Party Payors who made reimbursements for drugs purchased in Massachusetts, or who made reimbursements for drugs and have their principal place of business in Massachusetts, based on AWP for a Medicare Part B covered Subject Drug that was manufactured by [one of the Track 1 Defendants]." Final Class Order at 4-5, ¶ 1.

[7] As the Court is aware, it has certified Class 2 only under G.L. Ch. 93A. Final Class Order at 5, ¶ 4. Class 1 is certified for purposes of applying the consumer protection act of each state. Final Class Order at 3, ¶ 4. Plaintiffs presently seek partial summary judgment in favor of Class 1 only under G.L. Ch. 93A, which is being used as an examplar for purposes of potential collateral estoppel under other statutes.

evidence to support the nonmoving party's position. *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990).

"Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial." *Gillette Co. v. Energizer Holdings, Inc.*, 2005 U.S. Dist. Lexis 34122, at *5-6 (D. Mass. Dec. 19, 2005) (Saris, J.) (quoting *Barbour*, 63 F.3d at 37). "There must be sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." *Id.*, at *6 (quoting *Rogers*, 902 F.2d at 143). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Id.* (quoting *Barbour*, 63 F.3d at 36.

These standards mandate the entry of partial summary judgment against the Track 1 Defendants.

III. PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS

A. There Is No Genuine Issue Of Material Fact That AWP Was The Reimbursement Benchmark For Part B Drugs Under Medicare

There is no doubt that Class 1 and Class 2 Plaintiffs and class members made reimbursements for subject drugs based on AWP. As the Court has already recognized, Medicare Part B provided prescription drug coverage for approximately 450 drugs during the class period.[8] Seventeen of the 132 drugs at issue in this litigation were reimbursed under Medicare Part B, *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 69-70 (D.

[8] The class period for Class 1 and Class 2 is January 1, 1991 to January 1, 2005. Final Class Order at 7, ¶ 1.

Mass. 2005) (hereinafter "*In re AWP*"), including all of the physician-administered drugs at issue for each Track 1 Defendant.

As the Court has also found, "AWP was the basis for drug reimbursement under Medicare Part B for most of the . . . class period." *Id.* at 70. For brand name drugs, the reimbursement was 100% of AWP through 1997, 95% of AWP from January 1, 1998 through December 31, 2004, and 85% of AWP from January 1, 2004 to January 1, 2005. *Id.* (citing relevant federal statutes and regulations). For multi-source generic drugs, reimbursement was typically set at Maximum Allowable Cost ("MAC"), which is defined as the median of the AWPs of all generic forms of a drug. *Id.* (citing 42 C.F.R. § 405.517).

"Medicare pays 80% of the allowed amount of a covered drug, and the beneficiary is responsible for paying the other 20%." *Id.* at 71 (citing 42 U.S.C. § 1395l(a)(1)(S)). The 20%, called a "co-payment," is paid by the individual Medicare Part B aid recipient, or a Medi-Gap insurer. *Id.* The co-payment is, therefore, based on AWP.

There are no genuine issues of material fact regarding these findings. Plaintiffs' expert Meredith Rosenthal, has also concluded that AWP is "[redacted]" Ex. A (Rosenthal Liability Report, Dec. 15, 2005, at 5).[9] Dr. Rosenthal also concludes that "almost universally the drugs at issue in this case are reimbursed or paid for by endpayors using as a reimbursement benchmark the published AWP" and that "the proposed class is bound together by the use of AWP." Rosenthal Written Tutorial at 2 (Dkt. No. 1222).

[9] All exhibits cited in plaintiffs' Memorandum are attached to the Declaration of Steve W. Berman in Support of Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants submitted herewith.

As outlined below, even the Track 1 Defendants all recognized that Medicare Part B used AWP as the reimbursement benchmark during the class period.

1. AstraZeneca Agrees that AWP was the Reimbursement Mechanism for Part B Drugs

AstraZeneca's management and employees have unequivocally acknowledged that AWP was the reimbursement mechanism for Part B Drugs. *See* AZ Ex. 12 (Iacono Dep. at 125:21-126:8 (AstraZeneca's former Vice President of Marketing: "[redacted]"); AZ Ex. 13 (Black Dep. at 25:17-26:1 (Former President of Zeneca: "[redacted]"); AZ Ex. 26 (Brennan Dep. at 15:10-14 ("[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 5 (Buckanavage Dep. at 59-60 (Former Group Manager of Marketing Development: "[redacted]"), and at 112:13-20 ("[redacted]").

Thus, even at the highest levels of the company, AstraZeneca's executives knew and expected that Part B drugs, including Zoladex, would be billed to and paid for by the government, insurers and individual patients based on AWP.

2. BMS Agrees that AWP was the Reimbursement Mechanism for Part B Drugs

BMS "admits that Congress has mandated that Medicare Part B reimbursement be based, in part, upon AWP." Answer, ¶ 3 (Dkt. No. 800); *see also* BMS Ex. 7 (Plaintiffs' Interrogatories to the Fast Track Defendants, Response to Interrog. No. 11 ("both private and public payors have adopted an industry practice of using AWP as a benchmark for determining reimbursement rates . . . .")).

Not surprisingly, then, many senior BMS managers have testified that they understood that Medicare, as well as private reimbursement schemes, were based on AWP, including Dianne Ihling, BMS's former Director of Pricing and Institutional Operations;[10] Christof Marre, BMS's former Director of Marketing, Oncology;[11] Denise Kaszuba, BMS's Associate Manager of Pricing Support;[12] John Akscin, OTN's Vice President of Government Relations and Managed Care Services;[13] and Marsha Peterson, OTN's Western Sales Manager.[14]

3. GSK Agrees that AWP was the Reimbursement Mechanism for Part B Drugs

Glaxo marketing documents reflect repeated acknowledgement that AWP served as the basis for physician reimbursement under Medicare Part B. *See* GSK Ex. 1 at 14

[10] BMS Ex. 1 (Ihling Dep. at 90-93).

[11] BMS Ex. 2 (Marre Dep. at 49).

[12] BMS Ex. 3 (Kaszuba Dep. at 44-45).

[13] BMS Ex. 4 (Akscin Dep. at 26-27). Until 2005, OTN was a wholly-owned subsidiary of BMS and was the sales agent for BMS oncology products.

[14] BMS Ex. 6 (Peterson Dep. at 10).

(GlaxoWellcome Situation Analysis for 1996: "[redacted]"); GSK Ex. 2 at 3 (Glaxo document titled "Marketing Plans 1997": "[redacted]").

Similarly, SKB documents also reflect repeated acknowledgement that AWP served as the basis for physician reimbursement under Medicare Part B. The Kytril 1996 Market Situation Analysis states:

[redacted]

GSK Ex. 3 at 8.

The SB Oncology Sales Training Class Handbook confirms SKB's acknowledgement that AWP served as the basis for physician reimbursement under Medicare Part B:

[redacted]

[redacted]

GSK Ex. 4.

Based on SKB documents, there is no genuine dispute that AWP served as the basis for physician reimbursement of physician administered drugs under Medicare Part B.

4. J&J Agrees that AWP was the Reimbursement Mechanism for Part B Drugs

OBI's management and employees have unequivocally acknowledged that AWP was the reimbursement mechanism for Part B drugs. For example, Carol Webb, former President of OBI from 1994-2000, testified:

[redacted]

JJ Ex. 1 (Webb Dep. at 44-45). *See* JJ Ex. 2 (Pearson Dep. at 181 ("[redacted]")); JJ Ex. 3 (Hiriak Dep. at 202-03 ("[redacted]")). Despite being armed with such knowledge, OBI's management did not attempt to set Procrit AWPs to reflect the average price at which the drug was sold to providers or hospitals. *See* JJ Ex. 4 (Kling, former Manager of the OBI Contracting Department Dep. at 110 ("[redacted]")); JJ Ex. 2 (Pearson Dep. at 181 ("[redacted]

[redacted]")). Thus, even at the highest levels of the company, OBI executives knew and expected that Part B drugs, including Procrit, would be billed to and paid for by the government, insurers and individual patients based on AWP.

Centocor's President, Julie McHugh, also acknowledged that AWP was the basis for Medicare Part B reimbursement, in the context of discussing how Centocor set the initial AWP Remicade at a level that could allow physicians to profit from billing Medicare. *See* JJ Ex. 26 (McHugh Dep. at 160-161).

The importance of AWP was also admitted by Christine Poon, the Worldwide Chairman of Pharmaceuticals and Nutritionals and the corporate officer who had responsibility for all of the J&J operating companies that made pharmaceuticals, including Cenotocor and OBI. Ms. Poon stated that AWP is a benchmark that is used by payors for reimbursement, and that is why the J&J companies state an AWP. JJ Ex. 27 (Poon Dep. at 23-24).

5. Schering-Plough Agrees that AWP was the Reimbursement Mechanism for Part B Drugs

SPW has admitted that AWP as published in pharmaceutical industry pricing publications was a basis for reimbursement for SPW drugs covered by Medicare Part B.[15] Deposition testimony from key SPW executives also confirms that AWP was the benchmark for reimbursement. Jerome Sherman, Schering-Plough employee and National Sales Director for Warrick, admitted that "[redacted]"[16] Harvey Weintraub, a former VP for both Schering and Warrick acknowledged: "[redacted]

[15] ¶¶ 3 and 148 of SPW Answers to AMCC filed April 9, 2004 (Dkt. No. 777).

[16] SP Ex. 12 (Sherman Dep. at 46: 3-4).

[redacted]" (in determining the amount of reimbursement).[17] Debbie Kane, as the SPW Contract Manager, in explaining AWP to her staff, instructed: "[redacted]"[18] *See also* SP Ex. 39 (Cost Analysis for Superficial Bladder Cancer using the SP drug Intron-A showing AWP as the mechanism for Medicare Part-B reimbursement).

B. There is No Genuine Issue of Material Issue of Fact That Each Track 1 Defendant Caused AWPs To Be Published For Each Of Their Subject Drugs

Each of the Track 1 Defendants supplies AWPs directly or indirectly to the publishers. This occurs in one of two ways: either a Defendant sends an AWP or "suggested" AWP directly to a publisher, or a Defendant sends a wholesale list price ("WLP"), wholesale acquisition cost ("WAC") or Direct Price ("DP") to the publisher, and the publisher marks that price up (usually by either 20% or 25%) to achieve the reported AWP. Either way, the Defendant controls the AWP. Furthermore, each Track 1 Defendant used and republished the AWPs in various ways. A summary of the evidence on this issue against each Track 1 Defendant follows.

1. There is No Genuine Issue of Material Fact that AstraZeneca Caused AWPs for All of its Drugs, including Zoladex, to be Published

a. AstraZeneca set the published AWPs for all of its drugs, including Zoladex, prior to 2002

AstraZeneca openly admits that, prior to 2002, manufacturers set and controlled the AWPs for their drugs. *See, e.g.*, AZ Ex. 1 (Schultz Dep. at 102:19-20 ("[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 2 ([redacted]

[17] SP Ex. 13 (Weintraub Dep. at 332:6-7).

[18] SP Ex. 2 (Debbie Kane email to Contract and Pricing Staff, SPF0241686).

[redacted] ("[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 3 ([redacted] (admitting that the AWP is "[redacted]") (HIGHLY CONFIDENTIAL)).

As AstraZeneca's Director of Pricing Strategy explained:

[redacted]

AZ Ex. 4 ([redacted] (HIGHLY CONFIDENTIAL)).

AstraZeneca's marketing teams and pricing strategy managers made recommendations to management regarding whether, when and how much the AWP for Zoladex should be raised.[19] *See e.g.*, AZ Ex. 5 (Buckanavage Dep. at 150:2-12 (Market Development Manager believed his recommendations for setting AWP, if approved, would be passed along to publishers) (HIGHLY CONFIDENTIAL)); AZ Ex. 6 ([redacted] (discussing where to set the AWP for the launch of a new pack size of Pulmicort) (HIGHLY CONFIDENTIAL)); AZ Ex. 7 ([redacted]

[19] Interestingly, in or around 2000, AstraZeneca decided against raising the WAC for Zoladex because it believed FDB might lower the AWP-WAC spread from 25% to 20%, in essence reducing doctors' return to practice. *See* AZ Ex. 11 (Freeberry Dep. II at 64:9-21). Instead of changing AWP, AstraZeneca lowered the acquisition costs to doctors to create an increase in spread and return to practice. *See* AZ Ex. 51 (Davies Dep. at 102:9-12).

Patterson to Chris Iacono Re: Zoladex Pricing Strategy, [redacted] ("[redacted]

[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 8 ([redacted] (recommending increases to the published AWP for Zoladex and stating: "[redacted]") (HIGHLY CONFIDENTIAL)).

Approvals of new or revised AWPs came from the very top. *See, e.g.,* AZ Ex. 13 (Black Dep. at 42:7-16); AZ Ex. 9 (O'Shea Dep. at 28:1-19 (recommendations were approved by the VP of Marketing and endorsed by the President of the company) (HIGHLY CONFIDENTIAL)); AZ Ex. 5 (Buckanavage Dep. at 141:8-142:1 (approval was needed from senior management)); AZ Ex. 10 ([redacted] (setting out approval process and requiring that revised prices be approved by Finance, David Brennan (current CEO) and Legal Counsel) (HIGHLY CONFIDENTIAL)).

b. AstraZeneca communicated its AWP to the publishers for publication

Once a new or revised AWP was approved, AstraZeneca would inform the publishers. *See, e.g.,* AZ Ex. 11 (Freeberry Dep. I at 100:3-102:17, 109:2-110:9 (AZ would send periodic spreadsheets to First DataBank ("FDB") and the other publishers with AZ's AWPs.) (HIGHLY CONFIDENTIAL)); AZ Ex. 1 (Schultz Dep. II at 302:12-303:14 (same)); AZ Ex. 12 (Iacono Dep. I at 125:9-20 (same) (HIGHLY CONFIDENTIAL)); AZ Ex. 13 (Black Dep. at 50:12-51:2 (Zeneca informed the publishers whenever there was a price change) (HIGHLY CONFIDENTIAL)); AZ Ex. 12 (Reisenauer Dep. at 56:2-14 (he would pass on AstraZeneca's AWPs to another employee for publication in the RedBook) (HIGHLY CONFIDENTIAL)); AZ Ex. 15 ([redacted] (HIGHLY CONFIDENTIAL)); AZ Ex. 16 ([redacted] (noting that Freeberry will notify pricing services of Casodex and Nolvadex price increases) (HIGHLY CONFIDENTIAL)).

AstraZeneca's communications to the publishers were, as a practice, made in written form. *See, e.g.,* AZ Ex. 11 (Freeberry Dep. I at 110:1-6 (Pricing Strategy Director stating that spreadsheets containing AWP were sent to publishers with cover memos)); AZ Ex. 17 ([redacted] ("[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 17A ([redacted] (Revised Price List includes AZ's AWPs) (HIGHLY CONFIDENTIAL)); AZ Ex.18 ([redacted] (final pricing for Pulmicort Respules for publication) (HIGHLY CONFIDENTIAL)).

AstraZeneca also utilized the services of third-party consultants to communicate AWPs on its behalf. *See* AZ Ex. 20 ([redacted] (As of April 1996, AZ had authorized State and Federal Associates, Inc. ("S&FA"), a lobbying firm that focused on reimbursement issues, "[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 21 ([redacted] (model letter to be used to notify industry compendia of AZ price increases) (HIGHLY CONFIDENTIAL)); AZ Ex. 22 (Ware Dep. at 84:17-85:16 (S&FA employee stating she regularly sent letters communicating the AWP for Zoladex to publishers) (HIGHLY CONFIDENTIAL)).

c. AstraZeneca continued to "own" and cause the publication of its AWPs after 2001

Although AstraZeneca denies having set the AWPs for its drugs after 2001, it is clear that AstraZeneca adopted the AWPs set by FirstDataBank and perpetuated those AWPs by communicating them as their own to RedBook. *See, e.g.*, AZ Ex. 23 ([redacted] ("[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex. 24 ([redacted] ("[redacted]

[redacted]

[redacted]”)

(HIGHLY CONFIDENTIAL)).

Moreover, after 2001 AstraZeneca set the WAC knowing full well that FirstDataBank would publish AstraZeneca’s AWP at 125% of WAC. AZ Ex. 1 (Schultz Dep. II at 59:15-60:2 and 104:7-105:16 (AZ knew what the AWP would be when it submitted the WAC to FDB)); AZ Ex. 25 (Alverson Dep. I at 28:8-11 (“[redacted]

[redacted]

[redacted]”) (HIGHLY CONFIDENTIAL)).

2. There is No Genuine Issue of Material Fact that BMS Caused AWPs for All of its Drugs to be Published

BMS controls the AWPs published for its drugs by reporting “list” prices that are marked up 20 to 25 percent by various publishers including *Red Book* and *First DataBank*. After receiving the list prices from BMS, these publishers provide the AWPs to BMS. BMS implicitly approves these AWPs by using them in various ways, including: (i) distributing AWPs to a variety of BMS employees, including sales representatives; (ii) including AWPs on internal price lists; and (iii) publishing AWPs on the OTN website utilized by customers.

a. BMS controlled the AWPs for its Subject Drugs by reporting WLPs with full knowledge of the mark-up factors that the publishers would use to create the AWPs

BMS did not send AWPs directly to the publishers. Instead, BMS sent to the publishers a wholesale list price (“WLP”) or direct price, from which the publishers predictably calculated the AWPs. *See, e.g.*, BMS Ex. 7 (Plaintiffs’ Interrogs. to the Fast Track Defs., Response to Interrog. No. 11). In some instances, employees in BMS’s Pricing Support department would specifically

instruct the publishers to "[p]lease supply AWP's for these products once they have been processed through your database." *See, e.g.*, BMS Ex. 8 [redacted]; BMS Ex. 9 [redacted]; BMS Ex. 10 [redacted]; BMS Ex. 11 [redacted]; BMS Ex. 12 [redacted]; BMS Ex. 13 [redacted]; BMS Ex. 14 [redacted]; BMS Ex. 15 [redacted] "[redacted]")). Denise Kaszuba, BMS's Associate Manager of Pricing Support and the person responsible for reporting WLPs to the publishers and reviewing the AWPs established therefrom, readily admitted that the publishers reported an AWP using BMS WLPs as the base. BMS Ex. 3 (Kaszuba Dep. at 44).

The publishers would then send a report back to BMS showing the AWPs. BMS Ex. 7 (Plaintiffs' Interrogs. to the Fast Track Defs, Response to Interrog. No. 11). Pricing Support then reviewed the AWPs for reasonability and to determine the markup factor applied. BMS Ex. 3 (Kaszuba Dep. at 105-06); *see also* BMS Ex. 16 [redacted] ("[redacted]")); BMS Ex. 17 [redacted] and BMS Ex. 3 (Kaszuba Dep. at 149-50 (example of a Red Book product listing verification to BMS prices)); BMS Ex. 18 [redacted] and BMS Ex. 3 (Kaszuba Dep. at 151-52 (another example of Red Book product listing verification)).

BMS well understood the markup factors applied by the publishers to the BMS WLPs. The markup factor was 20% for most BMS drugs until 2000, when *First DataBank* changed it to

25%, BMS Ex. 3 (Kaszuba Dep. at 98-99), and BMS was always aware of the markups being used by all three publishers. *Id*. at 100-01. Moreover, BMS knew early in the class period how to effect changes to AWP and how this would directly affect reimbursement regimes based on AWP. For example, an internal Apothecon memo from 1993 discusses pricing strategy for two different lines of antibiotics. Recognizing that health plan reimbursements were typically based on AWP, the memo describes how Apothecon maintained two distinct AWPs for two sets of antibiotics: a high AWP line that "[redacted]" and a lower AWP line to facilitate third party plan use of the products because "[redacted]" BMS Ex. 19 ([redacted]). With more plans disallowing the high AWP line, and with MACs coming online, the memo advises that Apothecon has deleted the high AWP line and must now "[redacted]" *Id.* The memo then described how to accomplish this:

[redacted]

Id.

Other documents clearly demonstrate that BMS knew that it could effect precise changes in AWP through changes in its reported WLPs. *See, e.g.*, [redacted] (a document reviewing an August 2002 price increase for Glucophage XR determined that the price increase would result in a 111% increase in reimbursement amount based on AWP-15%)); BMS Ex. 21 ([redacted] (powerpoint recognizing that a 25% markup to WLP is

applied and that, consequently, a 7% price increase on Plavix translates into an 11% AWP increase and a 13% MCO increase based on a typical reimbursement formula of AWP – 13%)); BMS Ex. 22 ([redacted]) and BMS Ex. 3 (Kaszuba Dep. at 117-20 ("[redacted]

[redacted]

[redacted]

[redacted]

[redacted]")); BMS Ex. 23 ([redacted] (powerpoint titled "[redacted]

[redacted]" (April 2002) further confirms that BMS well knows how AWPs are set based on BMS WLPs)).

b. BMS "owned" the AWPs for its Subject Drugs

BMS made many uses of AWP. From 1995 through 2004, BMS produced an Internal Price List, which contained various prices including wholesale direct hospital pricing, federal supply schedule pricing, Public Health Service pricing, and AWP pricing from all three services. BMS Ex. 3 (Kaszuba Dep. at 46-47). AWPs were included on the Internal Price List at the request of marketing personnel, who were interested in AWPs because customers reimbursed based on AWP. *Id.* at 50-51. Pricing Support also licensed software from the publishers that displayed AWPs and would occasionally field calls from marketing personnel with requests for AWP information on both BMS drugs and the drugs of competitors. *Id*. at 50-55.

Throughout the 1990s, Pricing Support provided the BMS oncology sales force with a Pocket Reference Guide that contained AWPs from all three data services. *Id*. at 110-11. BMS typically updated and disseminated the Pocket Reference Guide when list prices changed. *Id.* at 112.

BMS's wholly-owned specialty distributor, OTN, continually republished the AWPs for BMS Subject Drugs. For example, the OTN periodic publication "[redacted]" reported AWPs taken from the Redbook. *See* BMS Ex. 24 ([redacted] (May/June 1994); [redacted] (November/December 1994); [redacted] (date unclear but Spring 1994)); BMS Ex. 25; BMS Ex. 26 (various issues from 1997-2000). As The Network News explained in the back of the bulletin under the caption "[redacted]":

[redacted]

OTN also published numerous online reports to which customers subscribed, including the "[redacted]" which contained a list of current AWPs for drugs that the client has previously purchased; and (ii) the "[redacted]" which contained the AWP for drugs that the client purchases, and the billing unit for each particular drug. OTN obtained the AWPs for both reports from the Red Book.

In sum, BMS controlled the AWPs for its Subject Drugs by sending prices to the publishers with knowledge of their markup factor. BMS also "owned" the AWPs for those drugs by continually republishing the AWPs.

3. There is No Genuine Issue of Material Fact that GSK Caused AWPs for All of its Drugs to be Published

GSK is responsible for the manufacture, marketing, and sale of the two competing drugs, Zofran and Kytril. These drugs, known as anti-emetics, are administered by physicians to

address chemotherapy-induced nausea. Although Glaxo and SKB were separate and competing companies until their merger in January 2001, they deployed remarkable similar strategies to market Zofran and Kytril. Both companies knew that oncology clinics made their anti-emetic purchasing decisions based on which products allowed them to maximize the profit, or "spread," between the price they paid for the products and the price at which they were reimbursed, and marketed their products to oncology clinics based on the spread. For both companies, successful execution of this marketing strategy depended on their ability to control the acquisition cost of their products, and to control the Medicare reimbursement amount, or average wholesale price ("AWP").

Glaxo and SKB controlled the AWP that was published by the pharmaceutical industry price reporting services through a two-step process. First, Glaxo and SKB, like any other manufacturer, set the wholesale price for their products. Second, Glaxo and SKB set the arithmetic ratio between the wholesale price and AWP that was relied upon by the pharmaceutical industry, including wholesalers, third-party payors, and the financial reporting services. When Glaxo and SKB increased the wholesale prices for their products, as they did on a regular basis, they communicated those new wholesale prices and the associated AWPs to wholesalers and TPPs. By controlling the ratio and communicating the AWPs to wholesalers and third-party payors, Glaxo and SKB controlled the AWP published by the pharmaceutical pricing reporting services. This control was vital to Glaxo's and SKB's marketing plans and, invariably, the AWPs that they communicated to wholesalers and third-party payors invariably were the AWPs that were published by the financial reporting services.

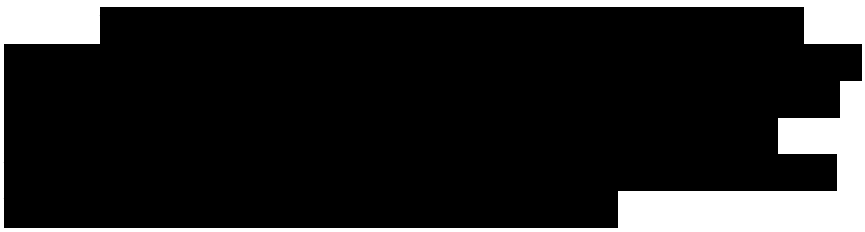
a. Glaxo controlled the AWP for Zofran

(1) Glaxo knew from the launch of Zofran that oncologists were driven by profit, and that Glaxo had to control the spread to maximize sales

Glaxo knew prior to Zofran's launch that it could control the AWP for Zofran, and that its control of the AWP would be instrumental to its successful marketing of the drug. In September 1990, five months before Zofran's launch, Carl Pelzel, who was the first Zofran Product Manager and later rose to the position of Director of Marketing of Glaxo's Oncology Division, wrote a memo acknowledging the "driving force" of the AWP/acquisition cost spread:

GSK Ex. 5 ( ).

Pelzel's pre-launch memo foreshadowed Glaxo's pricing strategy for Zofran in the short term and over the next 14 years. Indeed, Pelzel's early insight that Glaxo could use profit to physicians to increase sales of Zofran became a recurring theme in early Zofran marketing plans:



GSK Ex. 6 ( ) (emphasis added).

To pump up the Zofran's profitability for physicians and thereby increase Zofran sales, Glaxo had to control two price points: the physician acquisition price and the AWP. The physician acquisition price, a function of wholesale price and manufacturer discounting, was within Glaxo's complete control. And through setting wholesale prices for its products, and the ratio used to set the AWP based on those wholesale prices, Glaxo also controlled the AWP.

(2) Glaxo determined and announced the AWPs for its products

When Glaxo announced its new net wholesale prices ("NWP"), it simultaneously announced the AWPs associated with those prices. For example, on January 4, 1993, Al Goeken, who as Glaxo's Director, Trade Relations, managed Glaxo's dealings with wholesalers, sent a notice to all wholesalers announcing price increases for Glaxo products. The new prices were to take effect on January 5, 1993. Although the NWPs had not previously been released to wholesalers, third-party payors, the pharmaceutical industry price reporting services, or any persons outside Glaxo, the announcement listed not only the new NWPs, ***but also the new associated AWPs***. The letter also asked the wholesalers to "[redacted]" GSK Ex. 7 ([redacted]). Glaxo similarly reported simultaneously the new NWPs and associated AWPs for its products in other years. *See* GSK Ex. 8 ([redacted]); GSK Ex. 9 ([redacted]); GSK Ex. 10 ([redacted]).

Goeken was asked about Glaxo's practice of announcing the AWPs for its products ***before*** the products had actually been sold at the newly announced associated NWPs. Goeken testified that he was directed by Glaxo's Pricing Department to include AWP information in the

Glaxo new price announcement and that it was "[redacted]" in the pharmaceutical industry for pharmaceutical manufacturers to announce product AWPs simultaneous with their announcement of new wholesale prices. GSK Ex. 11 (Goeken Dep at 79-81). Goeken also testified that the information was transmitted to wholesalers so that they could include the product AWP information in their catalogues used by oncology clinic purchasers. *Id*. at 87-88.

Mr. Goeken also admitted that Glaxo determined the AWP for its products, and explained how:

[redacted]

Id. at 82. Many other Glaxo officials confirmed this testimony. *See, e.g.*, GSK Ex. 12 (Pelzel Dep. at 171-73 (acknowledging Glaxo calculated AWPs when considering price increases, and that "[redacted]")).

When Glaxo announced its new prices, NWPs and AWPs, it sent announcements not only to wholesalers, but also directly to third-party payors. *See, e.g.*, GSK Ex. 13 ([redacted]

[redacted] (announcing price increases to take effect January 10, 1995)); GSK Ex. 14 ([redacted] (announcing price increases to take effect March 7, 1996)). GSK would have no reason to send AWPs to third-party payors unless it understood that those AWPs would be published by the pharmaceutical price reporting agencies, and relied upon for reimbursement decisions by third-party payors.

(3) Glaxo controlled the ratio upon which AWP was based

As Mr. Goeken admitted, Glaxo did indeed determine the AWPs for its products. Glaxo, however, did not simply do the math; it also set the ratio upon which AWP was based. For Zofran, the ratio established between NWP and AWP, as Mr. Goeken testified, was 1:1.2. Put another way, the AWP for Zofran was 20 percent more than the NWP, or, in other words, the NWP for Zofran was less than the AWP by 16 2/3 percent.

For many years, when considering strategies to compete with SKB on Kytril, Glaxo considered changing the ratio. For example, in 1994, Glaxo was taken by surprise by kytril's immediate market penetration in oncology clinics, and sought a pricing strategy to compete. One strategy proposed by zofran Product Manager David Cory and submitted to Glaxo's Strategic Pricing Committee, a Glaxo policy-making committee comprised of Glaxo's senior managers, including Glaxo's CEO George Morrow, suggested increasing the ratio between NWP and AWP from 16 2/3% to 20%. GSK Ex. 15 ([redacted]). At his deposition, [redacted]

[redacted] GSK Ex. 16 (Cory Dep. at 53-56).

Glaxo's consideration of whether to change the NWP to AWP ratio persisted. In summer 1996, Glaxo retained Don Stark, whom Glaxo recognized to be an expert in the field of oncology product marketing who had performed over 20 consulting projects for Glaxo. In his proposed marketing plan to Glaxo, Mr. Stark also proposed increasing the NWP to AWP ratio:

[redacted]

GSK Ex. 17 ([redacted]). At his deposition, Mr. Stark was asked what Glaxo would do to change the NWP to AWP ratio for its products:

[redacted]

[redacted]

GSK Ex. 18 (Stark Dep. at 189-90).

So confident was Glaxo of its ability to control the NWP to AWP ratio that the recommendation to reset the ratio arose again in Glaxo's 1997 Marketing Plan for Zofran.

[redacted]

GSK Ex. 19 ([redacted]).

Through its control of its wholesale prices, and the ratio between its wholesale prices and the AWP for its products, Glaxo controlled the AWP that was published by the pharmaceutical industry price reporting services.

(4) Glaxo routinely considered the AWPs that would result from price increases when setting new prices

Any doubt that Glaxo controlled the AWPs that were published for its products is eliminated by analysis of Glaxo's consideration of price increases. *See, e.g.*, GSK Ex. 20 ([redacted] "[redacted]" of Zofran and its

competitor Kytril, and (iii) a computer printout entitled "[redacted]" setting forth the AWP for Zofran over time since launch)).

Indeed, at every turn, in connection with developing, considering, and approving price increases, Glaxo officials calculated the proposed AWP to the penny, and considered how that AWP would stack up against the competition. In December 1998, Zofran Product Manager Mike Yasick requested that Oncology Products Marketing Director David Robinson recommend a price increase for Zofran. Robinson performed an analysis of potential increase amounts, ***written in Robinson's own hand***, calculating the effect of a proposed price increase of 2%, 3%, 4%, 5%, and 6% on (i) the AWP for Zofran, (ii) the spread available to oncology clinics, and (iii) the difference in spread between Zofran, on one hand, and Kytril and Anzemet (a third competitor that reached the market in 1998), on the other. GSK Ex. 21 ([redacted]). Nowhere in the entire analysis, is there any mention of Glaxo's NWP for Zofran. The only dollar figure considered by Robinson is AWP.

b. SKB controlled the AWP for Kytril

(1) SKB knew that oncologists were driven by profit, and that SKB had to control the spread to maximize sales

SKB began marketing Kytril in March 1994. An early market situation analysis prepared by SKB marketing official S.A. Ross recognizes that SKB would have to provide favorable spreads to Kytril purchasers to compete in the anti-emetic marketplace, and that SKB would have to use its ability to set the AWP for Kytril in order to maximize purchaser spread.

B. Medicare

[redacted]

[redacted]

GSK Ex. 22 ([redacted] (emphasis added)).

Physician profit is the recurring and predominating theme throughout SKB's marketing plans over time. *See, e.g.*, GSK Ex. 23 ([redacted] ("[redacted]")); GSK Ex. 24 ([redacted] "[redacted]"). SKB understood that in order to inflate physician profit, it had to control the AWP for Kytril.

Nearly three years before the launch of Kytril, SKB recognized that it controlled the AWP for its products:

[redacted]

GSK Ex. 25 ((emphasis added)). Fish, who held senior positions with SKB since before the Kytril launch, and remains a GSK executive to this day, is explicit in his announcement that SKB controlled its wholesale prices, the ratio between its wholesale prices and AWP, the AWP for its products that were published by all pricing services, and the spread. Control of these elements was critical to SKB's ability to implement its marketing strategy.

(2) SKB determined the AWPs for its products by setting the WAC and setting the ratio between the WAC and the AWP

Even before the launch of Kytril, SKB knew that it could and would determine its AWP. David Pernock, VP Sales and Marketing, and Elizabeth Posner, Kytril Product Director, both recognized that SKB set the AWP for Kytril in order to compete with Zofran on the spread and knew precisely what the AWP for Kytril would be ***before the product went to market or any information was obtained by any price reporting service***:

GSK Ex. 26 ( ). The memo's authors also provided a table " " with columns identifying the " " " " and " " ***even before SKB announced the introduction of kytril or a single vial of kytril has been sold***. *See also* GSK Ex. 27 (" " and distributed to the nationwide sales staff prior to kytril launch)).

SKB knew even prior to Kytril launch that it would control the AWP for Kytril by controlling the wholesale acquisition cost ("WAC") and the ratio between WAC and AWP:

GSK Ex. 28 ((emphasis added)); *see also* GSK Ex. 27 ((conveying " ")).

Pearl Pugh, who served as a Kytril product manager from 1998 until the merger with Glaxo in 2001, acknowledged that SKB set the WAC/AWP ratio at " " GSK Ex. 30(Pugh Dep. at 94). Kevin Lokay, SKB Vice President and Director of Oncology Products, testified that the "

[redacted]" between WAC and AWP allowed SKB to calculate new AWPs for Kytril. GSK Ex. 31 (Lokay Dep. at 187-88).

SKB knew it could control the published AWP for its products by controlling the WAC and the WAC/AWP ratio, and did control the AWP that was published by the pharmaceutical price reporting services.

(3) SKB sent its suggested list prices to the pricing services, and knew the pricing services would report SKB's suggested list price as AWP

Prior to Kytril's launch, Horace Cook, SKB Trade Operations Director, detailed SKB's plan for notifying pricing services of the AWP for Kytril:

[redacted]

GSK Ex. 32 ([redacted]). SKB regularly communicated Kytril price increases to the pricing services. Reimbursement Manager Ashok Chainani testified that "[redacted]". GSK Ex. 33 (Chainani Dep. at 81).

SKB has denied setting AWP and has argued in its pleadings and through its witnesses that it only set a suggested list price. This assertion is belied by SKB's documents and admissions. SKB's use of the term "[redacted]" is an oblivious subterfuge. SKB's "[redacted]" list price was its AWP, SKB knew it, and SKB knew that its wholesalers, third-party payors, and

the pharmaceutical price reporting services knew it as well. Indeed, SKB employees explicitly defined "[redacted]" as "AWP." *See* GSK Ex. 25 ([redacted]); GSK Ex. 32 (Horace Cook defining in identical fashion). Elizabeth Posner testified that SKB used the terms "[redacted]" and "[redacted]" "[redacted]." GSK Ex. 34 (Posner Dep. at 128). Pearl Pugh testified that "[redacted]" GSK Ex. 30 (Pugh Dep. at 93). David Newman, a long time Kytril sales representative, marketing assistant, and product manager, testified similarly. GSK Ex. 36 (Newman Dep. at 68-69 ("[redacted]")).

The evidence is overwhelming that there is no genuine dispute that SKB transmitted "Suggested List Prices" to the pharmaceutical price reporting services, that when it did so it treated the term as interchangeable with AWP, and that the transmission would cause the publishers to publish the AWP provided by SKB.

(4) SKB regularly transmitted AWP information for Kytril to wholesalers and thirdpParty payors in advance of price increases

When SKB announced its new prices, it also transmitted to wholesalers and third-party payors the wholesale acquisition costs and suggested list prices, or AWPs, simultaneously. These transmissions were made ***in advance*** of the price increase taking effect. *See, e.g.,* GSK Ex. 37 ([redacted] (announcing price increase change effective March 26, 1996)); GSK Ex. 38 ([redacted] (announcing price increase change effective May 1, 1997)); GSK Ex. 39 ([redacted]

[redacted] (announcing price increase change effective October 30, 1998)); GSK Ex. 40 ([redacted] (announcing price increase change effective May 18, 1999)).

SBK also sent price change notifications to third-party payors. These announcements were sent on behalf of SKB by SKB's reimbursement consultant, Health IQ, and set forth the "New AWP" for Kytril. *See* GSK Ex. 41 ([redacted] (attaching draft and revised letters)). *See also* GSK Ex. 42 ([redacted] (directing Health IQ to develop a payor letter concerning price increases announced October 29, 1998)). SKB authorized Health IQ to transmit price change notifications, containing AWP and suggesting list price information to third-party payors, and Health IQ performed this service for SKB routinely:

[redacted]

GSK Ex. 43 (Chainani Dep. at 171-72).

(5) SKB routinely considered the AWPs that would result from price increases when setting new prices

Any doubt that SKB controlled the AWPs that were published for its products is eliminated by analysis of SKB's consideration of price increases. Virtually every document considering a change to Kytril wholesale acquisition cost contains an analysis of the impact of that change on Kytril's AWP, and a comparison of Kytril, Zofran, and Anzemet spreads. *See*

GSK Ex. 29 ([redacted] (setting forth March 1994 WACs and AWPs for Kytril and Zofran)); GSK Ex. 44 ([redacted] (setting forth WACs and AWPs for Kytril in setting forth March 26, 1996 recommended price increases)); GSK Ex. 45 ([redacted] (launch recommendation, setting forth AWP, cost, and profit information for various formulations of Zofran and Kytril)); GSK Ex. 46 ([redacted] (setting forth AWP, WAC, and Onc Supply (*i.e.*, cost) information for Kytril, Anzemet, and Zofran in connection with recommended and projected price increase); GSK Ex. 47 ([redacted] (setting forth AWP, WAC, and Onc Supply (*i.e.*, cost) information for Kytril, Anzemet, and Zofran in connection with recommended and projected price increase)).

There is no genuine issue of fact that SKB did not leave the setting and publication of the AWP for its products to the pharmaceutical price reporting services. Rather, through setting their own list prices, setting the ratio of list to AWP, calculating the AWP, and communicating the AWP to wholesalers, third-party payors, and the pricing services themselves, they cause the pricing services to publish the AWP they created.

4. There is No Genuine Issue of Material Fact that J&J Caused AWPs for All of its Drugs to be Published

a. J&J set the AWPs for Procrit and Remicade throughout the class period

There is no dispute that from the time Procrit was launched in 1991, OBI, with the approval and involvement of its parent company, ***set*** the list price (which at OBI is the equivalent

of WAC)[20] of all Procrit dosages. *See* JJ Ex. 2 (Pearson Dep. at 177); JJ Ex. 1 (Webb Dep. at 57-58). Moreover, it is undisputed that throughout the Class Period, OBI computed and ***set*** the AWPs of all Procrit by mechanically adding 20 percent to the list price of Procrit.[21] *See* JJ Ex. 2 (Pearson Dep. at 178-80 ("[redacted]"); *Id.* at 192 ("[redacted]")); JJ Ex. 5 (Dempsey Dep. at 92 ("[redacted]")); JJ Ex. 4 (Kling Dep. at 109-11 ("[redacted]")).

According to OBI witnesses, the purported reason for setting Procrit AWPs at a 20 percent markup over list price was the rather circular rationale that J&J was traditionally a "[redacted]" that typically calculated its drug AWPs at list price plus 20 percent. JJ Ex. 3 (Hiriak Dep. at 205-06). Although no OBI witnesses could provide a further explanation for the markup, OBI testimony uniformly established that the 20 percent markup was applied routinely and mechanically at the time of launch and every price change thereafter, irrespective of the actual costs of manufacturing Procrit, the actual costs connected with administering Procrit, or

[20] At OBI, list price means the wholesale acquisition price of the drug (WAC). JJ Ex. 2 (Pearson Dep. at 177); JJ Ex. 1 (Webb Dep. at 58).

[21] OBI witnesses have testified that beginning on June 8, 2004, OBI still sent publishers its Procrit list prices but no longer provided Procrit AWPs. However, First DataBank (FDB), this change in practice did not significantly affect OBI's control over the AWPs that were published, because OBI knew that major publishers other than FDB, such as Red Book, that did not receive AWPs from OBI would compute Procrit AWPs based on OBI's historical 20 percent markup over list price. *See* JJ Ex. 2 (Pearson Dep. at 179-80).

any discounts, rebates or chargebacks provided to Procrit customers. *See, e.g.*, JJ Ex. 4 (Kling Dep. at 109-11 ("[redacted]")); JJ Ex. 3 (Hiriak Dep. at 202); JJ Ex. 1 (Webb Dep. at 64-65 ("[redacted]")); JJ Ex. 6 (Reedy Dep. at 211 ("[redacted]")).

Similarly, before Remicade was launched in the United States in 1998, Centocor intentionally set the AWP at a level calculated to insure that physicians prescribing and infusing Remicade would make a profit. *See* JJ Ex. 28 ([redacted]). Further, Centocor's director of marketing (and current president) Julie McHugh confirmed at her deposition that it was important to set the price of Remicade at a level that would allow physicians to earn a profit. Setting the AWP so that providers (meaning physicians) would have a "[redacted]" was a "[redacted]" of the Remicade Launch Plan. JJ Ex. 26 (McHugh Dep. at 157-159). McHugh also explained that it was an important incentive to providers that they make money (or "[redacted]") from the administration of Remicade. *Id.* at 149-52.

J&J's control over the initial AWP is also revealed in its communication announcing the launch of Remicade. That letter contains only the AWP price, without any WAC or list price. *See* JJ Ex. 29 ([redacted]). Thus, even if a publisher wanted to

determine its own mark-up from WAC to AWP, the publisher would have no way to apply its calculations, since Centocor did not provide a WAC for Remicade – just an AWP.

b. J&J always controlled the AWP

The J&J parent company certainly believed that its pharmaceutical divisions set the WACs and AWPs of their respective drugs. On December 7, 2000, Robert G. Savage, the J&J Company Group Chairman for the J&J pharmaceutical group, sent an internal letter to several J&J pharmaceutical division Presidents (including Gary Reedy of OBI and David Holveck of Centocor), seeking information regarding the manner by which the divisions "[redacted]" the AWPs of their drugs:

[redacted]

JJ Ex. 7 ([redacted] (emphasis added)).

Likewise, the J&J parent certainly understood that the pharmacy divisions controlled the actual AWPs that were published for their respective branded drugs. Catherine Piech, a pricing expert for J&J's Pharmaceutical Group Strategic Marketing (PGSM) -- a J&J subsidiary responsible for approving strategic price actions of all J&J pharmaceutical divisions (JJ Ex. 1 (Webb Dep. at 54); JJ Ex. 2 (Pearson Dep. at 193)), sent a memo to OBI senior management dated on or about August 15, 2000, expressing her surprise that any entity other than J&J controlled the WACs and AWPs that were published for J&J drugs, stating: ("[redacted]

[redacted])" JJ Ex. 8 ([redacted] (emphasis added)).

Indeed, throughout the Class Period, OBI dictated the AWPs that were published in industry compendia for Procrit. More specifically, at the time of launch and every Procrit price change prior to June 2004, OBI sent a communication to all of the major publishers announcing the new list prices and corresponding AWPs that OBI had calculated internally for Procrit. JJ Ex. 3 (Hiriak Dep. at 203-04). The AWPs that OBI sent to publishers were neither "[redacted]" nor "[redacted]" *See, e.g.*, JJ Ex. 9 ([redacted] (referred to by OBI in 1997 as "[redacted]")); JJ Ex. 10 ([redacted] (referred to by OBI in 1998 as "[redacted]")); JJ Ex. 11 ([redacted] (referred to by OBI in 2000 as "[redacted]")). Rather, OBI intended and expected the new AWPs to be published by the compendia. *See* JJ Ex. 5 (Dempsey Dep. at 94 ("[redacted]")); JJ Ex. 1 (Webb Dep. at 66-67 ("[redacted]")). And, as OBI witnesses uniformly testified, they could not recall a single instance when the prices provided by OBI were not published. *See, e.g.*, JJ Ex. 3 (Hiriak Dep. at 214-15 ([redacted]

[redacted]”)); JJ Ex. 4 (Kling Dep. at 116 (“[redacted]”)).

OBI knew that clinics, physicians, hospital outpatient clinics and providers who purchased Procrit billed private insurers, patients and Medicare based on a percentage of AWP. JJ Ex. 12 (Dooley Dep. at 110-11, 164-65); JJ Ex. 4 (Kling Dep. at 105). OBI's management also was aware that public and private insurers used the compendia to learn the AWPs of drugs for reimbursement purposes. JJ Ex. 4 (Kling Dep. at 105); JJ Ex. 1 (Webb Dep. at 67-68).

Nor can there be any doubt that Centocor determined Remicade AWPs. In an email exchange between Joseph Scodari, then a J&J executive overseeing Centocor, Dave Holveck, a former president of Centocor, and Tony Vernon, the incoming president of Centocor, Scodari admits several times that Centocor controls the AWP for Remicade:

[redacted]

JJ Ex. 30 ([redacted] (emphasis added)); *see also* JJ Ex. 31 (Scodari Dep. at 19-20).

Even before Remicade was launched in the United States in 1998, Centocor intentionally set the AWP at a level calculated to insure that physicians prescribing and infusing Remicade would make a profit. The strategy is plainly identified in the initial Remicade Marketing Plan (titled cA2 Marketing Plan) of May 1998, (stating “[redacted]”) as a goal of the pricing strategy), see pgs. 97 and 147-49, attached as JJ Ex. 28. Further, Centocor's director of marketing (and

current president) Julie McHugh confirmed at her deposition that it was important to set the price of Remicade at a level which would allow physicians to earn a profit. Setting the AWP so that providers (meaning physicians) would have a "[redacted]" was a "[redacted]" of the [redacted], JJ Ex. 28 and JJ Ex. 26 (McHugh Dep. at 157-59). McHugh also explained that it was an important incentive to providers that they make money (or "[redacted]") from the administration of Remicade. JJ Ex. 26 (McHugh Dep. at 149-52 and 91-92).

Centocor's control of the AWP price is further evidenced by the mechanism by which Centocor announced prices changes for its products. At the very same time Centocor announced a change to the WAC price for Remicade, it also announced what the new AWP price would be. In deposition, Centocor's John Hoffman confirmed that the new AWP price was calculated internally by Centocor. No one at Centocor contacted publishers to ask them what AWP they would be stating based on the new WAC prices, or to ever confirm that publishers would accept the new AWP stated by Centocor. In fact Centocor never even considered what would happen if the publishers did not use the Centocor AWP. This is because Centocor understood that the publisher would automatically accept and publish the new AWP pricing announced by Centocor. JJ Ex. 32 (Hoffman Dep. at 129-32, 136-37).

5. There is No Genuine Issue of Material Fact that Schering-Plough Caused AWPs for All of its Drugs to be Published

In their answers, both SP and Warrick admitted to reporting pricing information for their medicines to pharmaceutical industry pricing publications.[22] However, SPW did not merely report "pricing information"; SPW reported AWPs that it had sole responsibility for creating.

[22] These admissions are contained in ¶¶ 3 and 481 of Warrick's and SP's Answers to Intervenor's Amended Master Consolidated Class Action Complaint filed April 9, 2004 (Dkt. No. 777).

Discovery has confirmed conclusively that SPW controlled and set the AWPs for its products.[23] After setting the AWPs, SPW caused the AWPs to be published in pharmaceutical pricing compendia[24] and, thereafter, advertised the AWPs directly to customers.[25]

C. There is No Genuine Issue of Material Issue of Fact That (i) The AWPs That Each Track 1 Defendant Caused To Be Published Neither Reflected An Average Nor Included The Discounts Called For By OIG Guidelines, and (ii) Each Track 1 Defendant Manipulated And Marketed Spreads

As the Court has already recognized, from 1992 to 1997 Medicare Part B reimbursement was based on the lesser of estimated actual cost ("EAC") or AWP, with Medicare carriers choosing to rely on AWP. *In re AWP*, 230 F.R.D. at 70 (citing 42 C.F.R. § 405.517, amended Nov. 2, 1998, Jan. 7, 2004 and Nov. 15, 2004). AWP was not defined in any statute or regulation, but, as the Court noted, "EAC was supposed to be measured through surveys conducted by regional Medicare administrators (termed 'carriers'), who were to determine the usual and customary charge ('U&C') for a geographic area." *Id.* On January 1, 1998, reimbursement for single-source drugs was changed to the lesser of (i) the billed charge on the

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[23] With regard to Warrick generics, in a June 21, 2000 letter from SPW attorney, John Hoffman, to L. Timothy Terry, OAG – Nevada, SP Ex. 1 ([redacted]), Hoffman admits on behalf of Warrick: "[redacted]".. For Schering brands, in a May 5, 2000 email from Debbie Kane, SPW Contract Manager, to Contract and Pricing Staff, [redacted], Kane stated: "[redacted]" SP Ex. 2; *see also* SP Ex. 3 (Zahn Dep.at 176-77 (SPW0039627-28) (Pres. of Schering Laboratories) ("[redacted]").

[24] There are many examples of Western Union Mailgrams and faxes from Schering and Warrick to *First DataBank* and *Redbook*. *See, e.g.*, SP Ex. 4 ([redacted]); SP Ex. 5 ([redacted]); SP Ex. 6 ([redacted]); SP Ex. 7 ([redacted]).

[25] *See* SP Ex. 3 (Zahn Dep. at 95-96 ([redacted]) ("[redacted]")). Also, a standard SPW marketing practice for Warrick generics was to advertise the spread by sending notices to customers of price changes showing the static AWP juxtaposed next to the new lower net direct price. For example, *see* SP Exhs. 8 and 9. Certain offers for generics would also show AWP, cost and "[redacted]" *See* SP Ex. 10 ([redacted]). SP also sent similar notices for branded drugs advertising AWPs juxtaposed to net direct pricing. *See, e.g.*, SP Ex. 11 ([redacted]).

Medicare claim form or (ii) 95% of AWP. *Id.* (citing 42 U.S.C. § 1395u(o), amended Dec. 8, 2003; 42 C.F.R. § 405.517). On January 1, 2004, Congress again modified the reimbursement level, this time adopting 85% of AWP. *Id.* (citing 42 U.S.C. § 1395u(o); 42 C.F.R. § 414.707).

The Court has also recognized that, "[b]ecause the carriers never conducted the surveys of EACs, AWP became the basis for most Medicare reimbursement. *Id.* (citing Rosenthal report at 7). "The government utilized the AWPs listed in the pricing publications, which follow defendants' pricing instructions." *Id.*

This history demonstrates that Congress intended Medicare Part B reimbursements to reflect actual costs in the marketplace ***or be at least reasonably related thereto***, whether the reimbursement formula was the lesser of EAC or AWP, the lesser of the billed charge or 95% of AWP, or 85% of AWP. Indeed, in tracing the history of Medicare Part B's reliance on AWPs, Dr. Meredith Rosenthal highlighted the explicit link between the Social Security Act Amendments of 1965 and real costs: "The amount paid to any provider of services with respect to services for which payment may be made . . . shall . . . be the reasonable cost of such services . . . ." Written Tutorial of Dr. Meredith Rosenthal at 6 (citing P.L. 89-97) (Dkt. No. 1222). As Dr. Rosenthal also reported, Robert Ball, who served as commissioner of Social Security under Presidents Kennedy, Johnson and Nixon, explained that, in connection with drugs administered in a physician's office, "[r]eimbursement was to be a '***reasonable***' charge determined by the customary charges of the particular physician and the prevailing charges in the locality for similar services." *Id.* (quoting Ball, R.M., 1995, *What Medicare's Architects Had in Mind,* HEALTH AFFAIRS, 14(4), at 68-69) (emphasis added).

These historical touchstones demonstrate that Congress always intended Medicare Part B drug reimbursement to be reasonably related to prevailing costs in the marketplace and not some

fictitious, inflated standard. Furthermore, these touchstones are consistent with the well-established canon of statutory construction that by "using terms undefined in the statute, Congress intended the words to have their natural, ordinary and familiar meaning." *United States v. 525 Co.*, 342 F.2d 759, 761 (5th Cir. 1965) (citing *First Nat'l Bank of Cincinnati v. Flershem*, 290 U.S. 504 (1934)); *see also FDIC v. Meyer*, 510 U.S. 471, 476 (1994) (When Congress leaves a term in a statute undefined, it is the duty of the federal courts to construe the term "in accordance with its ordinary or natural meaning.") (referring to BLACK'S LAW DICTIONARY to define the word "cognizable," which Congress left undefined in 28 U.S.C. § 1346(b)); *Smith v. United States*, 508 U.S. 223, 228 (1993) (referring to both BLACK'S LAW DICTIONARY and WEBSTER'S NEW INTERNATIONAL DICTIONARY to define the word "use," which Congress left undefined in 18 U.S.C. § 924(c)(1).).

The word "average" can mean "a mean proportion, medial sum or quantity, made out of unequal sums or quantities," BLACK'S LAW DICTIONARY at 135 (6th ed.) (hereinafter "Black's"), or simply "typical" or "usual." AMERICAN HERITAGE DICTIONARY at 144 (2d ed. 1991). Black's defines "wholesale price" as "that which retailer pays in expectation of obtaining higher price by way of profit from resale to ultimate consumer." Black's at 1597. Read together and applied in this context, the natural, ordinary and familiar meaning of "average wholesale price" is a mean proportion or medial, or a typical or usual, amount that intermediaries pay before resale to the ultimate consumers.

Recent official proclamations validate both this simple construction and the legislative history. For example, the former Administrator of the Centers for Medicare & Medicaid Services, Thomas Scully, testified, while Administrator, that "the AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians

and pharmacies." *See* Ex. B (March 14, 2002, *Testimony of Thomas A. Scully, Administrator of Centers for Medicare & Medicaid Services, on Reimbursement & Access to Prescription Drugs under Medicare Part B, Senate Finance Committee, Subcommittee on Health* at 5). Even more recently, the Office of the Inspector General at the United States Department of HHS ("OIG") clearly explained that the AWP must be a meaningful figure that is not artificially inflated, and that the "government sets reimbursement with the expectation that the data provided are complete and accurate." Ex. C (OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, at 23733 (May 5, 2003).

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Id. at 23733-34.

Those same guidelines also establish that purposeful AWP manipulation is an unlawful practice:

> (c) Average Wholesale Price. The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. ***In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.***
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute***. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

Id. at 23736-37 (emphasis added).

The Court, in carrying out the "heartland task of construing statutory language,"[26] must provide due deference to these agency interpretations. *See Harrington v. Chao*, 280 F.3d 50, 59 (1st Cir. 2000) (Judicial deference to agency interpretations is premised in part on the notion that agencies have greater expertise in their area of specialty than do courts) (citing *Chevron, U.S.A. Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837, 836-66 (1984)).

[26] *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 180-81 (D. Mass. 2003).

At a bare minimum, the foregoing means that each Track 1 Defendant was under a legal obligation to include relevant discounts in their AWPs and to otherwise refrain from manipulating AWPs and/or marketing spreads based on those AWPs. But as the overwhelming and undisputed body of critical evidence demonstrates below, each Track 1 Defendant chose the darker path by (i) failing to include relevant discounts in the AWPs that they controlled, (ii) manipulating spreads between AWPs and actual costs in the marketplace, and (iii) actively marketing those spreads.

1. There is No Genuine Issue of Material Fact that AstraZeneca's AWPs Neither Reflected an Average nor Met OIG Guidelines, and that AstraZeneca Purposefully Manipulated And Marketed Spreads

a. AstraZeneca manipulated the AWPs of its Subject Drugs

There is no evidence, and thus no genuine issue of material fact, that AstraZeneca's AWPs were anything but arbitrary. A former Pricing Strategy Manager for AstraZeneca described AstraZeneca's AWPs as:

[redacted]

AZ Ex. 1 (Schultz Dep. II at 107:2-9); *see also id.* at 311 (… "[redacted]"). Similarly, AstraZeneca's Vice President of Marketing described AWP as "[redacted]" AZ Ex. 12 (Iacono Dep. I at 125:10-11). *See also* AZ Ex. 46 (Liebman Dep. at 88:12-19 (the Sales Director for the Trade Segment: AWP "[redacted]") and 131:12-21 (acknowledging that AWP was referred to by some in the industry as "[redacted]") (HIGHLY CONFIDENTIAL)); AZ Ex.

47 (McAlister Dep. at 115:3-10 (Contracting Director for Oncology: AWP did not represent either an actual or average cost) (HIGHLY CONFIDENTIAL)).

For example, in recommending that AstraZeneca should raise the AWP and lower discounts for Zoladex in 1996, AstraZeneca's marketing team tried to cover its tracks, stating "[redacted]" AZ Ex. 7 ([redacted] (HIGHLY CONFIDENTIAL)). Yet, the Group Manager for Market Strategy and Contract Operations (who was cc'd on that memo) testified that AstraZeneca never conducted (or considered conducting) an analysis of increased manufacturing costs, nor was any consideration given to historical realized revenue per unit in setting AWP. AZ Ex. 5 (Buckanavage Dep. at 195:3-17).

AstraZeneca's knowing failure to give AWP any true meaning dates back to 1994 when AstraZeneca's current Director of Pricing Strategy, John Freeberry, was asked by the Company to research whether to change the spread on Company drugs from 25 to 20 percent. AZ Ex. 11 (Freeberry Dep. I at 167-76 (HIGHLY CONFIDENTIAL)). During the course of that research, Freeberry discovered that AWP was "[redacted]" – that it was not based on anything at all:

[redacted]

[redacted]

AZ Ex. 11 (Freeberry Dep. I at 168:6-20). He immediately reported this up the chain of command. *Id*. at 172:11-73:3. But despite his discovery, neither he nor AstraZeneca did anything about it. *Id*. at 173:9-76:6.[27]

AstraZeneca purposefully refrained from taking any steps to make AWP a meaningful number, because it wanted to remain competitive, albeit on a deceptive basis. Mr. Freeberry explained that:

[redacted]

AZ Ex. 11 (Freeberry Dep. I at 175:11-20 and 176:3-6). Thus, rather than give meaning to AWP, AstraZeneca made the deliberate decision to perpetuate the gaming of the system.

Mr. Freeberry, who subsequently became the head of the department charged with setting prices for AstraZeneca's pharmaceuticals, took on the responsibility of analyzing whether to increase prices from time to time on the Company's existing brands. In undertaking this process, AstraZeneca generally hired an outside consultant to send out questionnaires to various customers, including physicians, retailers, PBMs, hospitals, and long-term care facilities. *Id.* at

[27] Mr. Freeberry's "[redacted]" as well as the testimony of Eric Q. Schultz, former Pricing Strategy Manager at AstraZeneca, that Mr. Freeberry's research was put into a "[redacted]" and newsletter for the purpose of educating AstraZeneca employees regarding what AWP was, completely undermines the defense that "[redacted]" what AWP was. *See* AZ Ex. 1 (Schultz Dep. II at 182-85). It appears that no one at AstraZeneca, not even the Pricing Strategy Director, knew that AWP was fictitious.

27:17-33:6. However, even though Freeberry had done the research on AWP – and could have directed that questionnaires be sent to wholesalers in order to fix AWP, he never did so. He and AstraZeneca chose not to do so because, as Freeberry testified, what wholesalers paid did not impact AstraZeneca's business. *Id*. at 32:17-18. That is true in light of the fact that AZ has historically controlled the AWP, ensuring that it is not tied to what wholesalers actually pay. *See* AZ Ex. 48 ([redacted] (HIGHLY CONFIDENTIAL) ("[redacted]")).

Thus, throughout the Relevant Period, AstraZeneca's strategies exploited the malleability of pharmaceutical pricing, noting that AWP is an "[redacted]" (*see* AZ Ex. 49 ([redacted] (HIGHLY CONFIDENTIAL)), and that WAC is a figure that can "[redacted]" when necessary to maximize physician profit (*see* AZ Ex. 50 ([redacted] (HIGHLY CONFIDENTIAL)).

Yet, at least one Pricing Strategy Manager, Erik Schultz, explained that he thought it was "[redacted]" for AstraZeneca to evaluate and increase the AWPs for Zoladex based on whether physicians were making enough profit. Despite Mr. Schultz's resistance, AstraZeneca did it anyway. AZ Ex. 1 (Schultz Dep. II at 93:21-95:4 and 124:10-129:8 ("[redacted]")).

b. AstraZeneca communicated its AWPs to the sales force for the purpose of marketing the reimbursement mechanism to its physician customers

Sales management and marketing managers communicated to the sales force the current AWPs for Zoladex for communication to physician customers who bought Zoladex because the AWPs affected the physicians' reimbursement and profit, referred to at AstraZeneca as the physician's Return to Practice. *See e.g.*, AZ Ex. 27 (Patterson Dep. at 267:1-268:16 (stating that sales reps were given materials delineating return to practice scenarios, prices and discounts) (HIGHLY CONFIDENTIAL)); AZ Ex. 28 (Simpson Dep. at 75:20-77:22 (stating that the difference between AWC and AWP was contained in selling sheets) (HIGHLY CONFIDENTIAL)).

[redacted]

See AZ Ex. 29 (Bowman Dep. at 37:14-22) (HIGHLY CONFIDENTIAL). *See also* AZ Ex. 30 ([redacted] encouraging sales force to communicate orally with physicians regarding, *inter alia*, guaranteed current Zoladex pricing (AWP and AWC) (HIGHLY CONFIDENTIAL)); AZ Ex. 10 ([redacted] (setting out approval and communication process for price changes) ([redacted]) (HIGHLY CONFIDENTIAL)).

The sales force pushed Zoladex purchases by marketing the AWP Spread and thus ensuring that Return to Practice became a promotional emphasis. AZ Ex. 14 (Reisenauer Dep. at 39:1-12); AZ Ex. 27 (Patterson Dep. I at 63:14-17). They did so through multiple avenues, including by:

- Using spreadsheets during sales calls showing the AWPs for Zoladex, Medicare and patient reimbursement, physician costs, and the Return to Practice, *see e.g.*, AZ Ex. 31 (Email dated January 3, 1999 with attached spreadsheet entitled "[redacted]" ([redacted]) (HIGHLY CONFIDENTIAL)); AZ Ex. 29 (Bowman Dep. at 76:9-78:14) (HIGHLY CONFIDENTIAL); AZ Ex. 32 (Henkel Dep. at 90:13-92:22) (HIGHLY CONFIDENTIAL); AZ Ex. 33 (Klein-Zignoli Dep. at 95:5-96:2) (HIGHLY CONFIDENTIAL); AZ Ex. 27 (Patterson Dep. at 65:5-67:9) (HIGHLY CONFIDENTIAL); AZ Ex. 34 (Robbins Dep. at 23:9-25:8) (HIGHLY CONFIDENTIAL); AZ Ex. 35 (Ryan Dep. at 85:7-86:8) (HIGHLY CONFIDENTIAL); AZ Ex. 36 (Wawrzonek, Regional Oncology Account Manager, Dep. at 58:3-59:4 (stating that he knew sales reps prepared such visual aids to present to doctors and did not object to them being used) (HIGHLY CONFIDENTIAL)); AZ Ex. 37 (Berkman Dep. at 94:9-12 (HIGHLY CONFIDENTIAL).

- Answering physician's questions regarding how much Medicare reimbursed for Zoladex (AWP-based), how much the patient would reimburse the physician (the co-pay), how much the physician would pay to purchase Zoladex, and the profit that the physician could make by purchasing Zoladex rather than Lupron, *see, e.g.*, AZ Ex. 38 (Mastrangelo Dep. at 166:5-169:6) (HIGHLY CONFIDENTIAL); AZ Ex. 39 (Metcalf Dep. at 28:3-13) (HIGHLY CONFIDENTIAL); AZ Ex. 29 (Bowman Dep. at 37:14-40:15, 64:4-14) (HIGHLY CONFIDENTIAL); AZ Ex. 35 (Ryan Dep. at 84:2-21) (HIGHLY CONFIDENTIAL); AZ Ex. 41 (Notes from Regional Consultancy Meeting in July 1997 ([redacted]) ("[redacted]")).

- Using off-invoice discounting to ensure full reimbursement based on AWP. *See* AZ Ex. 41 (Handwritten Note (stating: "[redacted]") AZ0037022) (HIGHLY CONFIDENTIAL)); AZ Ex. 42 (7/26/96 Memorandum dated July 26, 1996 from a consultant to the Zeneca File Re: Conversation with Mark Reisenauer (stating "[redacted]")

( ) (HIGHLY CONFIDENTIAL)); AZ Ex. 43 (, at 13) (HIGHLY CONFIDENTIAL) (“ ”)); AZ Ex. 27 (Patterson Dep. II at 333:18-334:3) and AZ Ex. 37 (Berkman Dep. at 185:21-186:6 (AZ Associate Director of Marketing for Oncology and a urologist confirm that volume discounts were not reflected on Zoladex invoices)).

- Sending letters to potential accounts encouraging them to switch to Zoladex based on the current AWPs, cost to physicians and resulting Return to Practice versus Lupron, *see* AZ Ex. 44 (“ ” Group ( ) (HIGHLY CONFIDENTIAL) (comparing same and stating “ ” (emphasis in original)); AZ Ex. 45 ((comparing same and stating “ ” (emphasis in original)).

2. There is No Genuine Issue of Material Fact that BMS’s AWPs Neither Reflected an Average nor Met OIG Guidelines, and that BMS Purposefully Manipulated And Marketed Spreads

In addition to republishing its own AWPs, BMS manipulated the real prices at which BMS Subject Drugs were sold in order to take advantage of disparities between AWPs and actual acquisition prices. It then marketed the spread.

a. BMS knew that its Subject Drugs were sold at prices well below AWP

Several BMS documents demonstrate that BMS AWP as a fictitious number even though BMS knew that Medicare Part B reimbursements were based on AWP. For instance, an “Executive Summary” regarding a proposed plan by New England legislators to form a six-state purchasing group reviewed pricing in the distribution channel and recognized that no one pays AWP. “

[redacted]" The document also recognized that AWP was a "joke:"

[redacted]

BMS Ex. 31 ([redacted]). Indeed, a document titled "[redacted]" declares that the First Databank 20-25% AWP markup is an "[redacted]" and that "[redacted]" BMS Ex. 32 ([redacted]).

An "[redacted]" and that there is a "[redacted]" BMS Ex. 32 ([redacted]). Most importantly, perhaps, BMS recognized that "[redacted]" and that it consequently "[redacted]" BMS Ex. 34 ([redacted] (emphasis added)).

Despite recognizing that AWP is fictitious, misleading and confusing, and that, nonetheless, public and private payers rely upon it as a reimbursement benchmark, there is no evidence that BMS ever took any actions to either persuade publishers to report accurate AWPs or to publicize the inflated nature of the AWPs for BMS or other drugs. Indeed, senior managers testified that (i) they never conducted surveys of wholesale prices to determine whether the

AWPs being reported for BMS drugs were accurate, or (ii) were not concerned that false AWPs were being published for BMS products. Examples include:

Instead of taking action to correct AWPs, BMS adopted them as its own, distributing AWPs throughout the sales organization and republishing AWPs to customers. Why? Because BMS believed that the maintenance of spread on its drugs was important in gaining and

maintaining market share. As the following sections will demonstrate, BMS manipulated the spread between AWP and actual acquisition prices in the marketplace through secret discounting and rebating mechanisms. BMS then actively promoted and marketed the spread.

b. Recognizing the importance of spreads, BMS created spreads through confidential contract pricing, rebates and other forms of discounting

(1) The importance of reimbursement

BMS recognizes that reimbursement issues are very important to physicians working in office-based oncology practices ("OBOs"). This is emphasized in many documents and was acknowledged by numerous witnesses. For instance, John Akscin, OTN's current Vice President of Government Relations and Managed Care Services, whose former title was Director of Business Development for Office Based Oncology, BMS Ex. 4 (Akscin Dep. at 14, 78-80), emphasized in a Powerpoint presented to OTN and BMS sales representatives that the "[redacted]" were "[redacted]", "[redacted]" and "[redacted]" *Id*. at 89; BMS Ex. 46 ([redacted]. Indeed, Akscin acknowledged that OBO revenue is "[redacted]" because 50-55% of OBO patients are Medicare recipients, BMS Ex. 4 (Akscin Dep. at 91-92), and that 64 percent of OBO revenues came from drug reimbursements. BMS Ex. 4 (Akscin Dep. at 93).[28]

An undated document regarding "[redacted]" echoed this conclusion, estimating that "[redacted]" that drug reimbursements are based on AWP, and that "[redacted]" Indeed, "[redacted]

[28] Part of Akscin's responsibilities also included daily discussions with OTN clients that were referred to him by sales reps. Topics discussed included drug reimbursement issues and AWPs. BMS Ex.4 (Akscin Dep. at 57-58). In fact, Akscin sometimes provided specific AWPs to the clients, which he obtained from Red Book or FDB. *Id.* at 58.

[redacted]” In addition, “[redacted]” BMS Ex. 36 ([redacted]). Not surprisingly, then, another Akscin powerpoint stated “[redacted]” BMS Ex. 37 ([redacted]

OBO reimbursement concerns were so important that BMS and OTN offered various reimbursement consulting services to their clients. OTN hired KR Johnson & Associates (“KRJ,” now called Practice Expert) to train OTN employees on how OBOs operate, including billing and reimbursement methods. BMS Ex. 4 (Akscin Dep. at 18-20). The billing and reimbursement part of the training included discussions of AWP “[redacted]” *Id*. at 26. Akscin also referred OBOs to KRJ from time-to-time. The services that KRJ would provide to OTN customers included setting up billing and reimbursement systems. *Id*. at 22-24. Customers reported that they valued the services that KRJ provided. *Id*. at 43-44.

From before 1999 until sometime in 2003, OTN also offered a reimbursement assistance program in the form of a reimbursement hotline provided by a company called DocuMedix (subsequently purchased by the Lash Group). *Id*. at 35-36. The assistance that DocuMedix provided to OTN customers included conveying information regarding billing codes, disease classification codes, billing units and AWPs. *Id*. at 37-38. Akscin confirmed that OTN customers valued the DocuMedix service that was offered, and OTN actually marketed the

service. *Id.* at 42-43. For examples of "[redacted]" that refer to reimbursement assistance support, *id.* at 122-23, see BMS Ex. 39 ([redacted].

BMS also offered its clients the ProCert service through ProStat. BMS Ex. 4 (Akscin Dep. at 31). ProCert "[redacted]" *Id.* at 33. ProCert takes over the claim after initial denial of reimbursement and serves as the client's advocate. Historically, if the claim was ultimately paid, then BMS billed for the drug. If not, OTN would credit the account with free drug. The program later changed such that the customer paid for the drug up front and then received a credit if ProCert was successful in getting the claim paid. BMS Ex. 39 (Soule Dep. at 132-35). Soule confirmed that ProCert is another sales incentive that is marketed to customers as part of the total package that BMS brings to the client. *Id.* at 132.

Reimbursement is so important that BMS identified "[redacted]" as a threat to its business. BMS Ex. 40 ([redacted]). And BMS lobbied the federal government to maintain AWP-based reimbursement for Part B drugs:

[redacted]

[redacted]

BMS Ex. 41 ([redacted]). The memo closes with a request to add personnel to the Policy Department given that "[redacted]" *Id.*

(2) Creating spreads

In order to play to OBO concerns about reimbursement, BMS created spreads through special contract pricing and other discounting methods. The former Director of Marketing for Oncology, Christof Marre, testified to the various ways in which BMS provided discounts off of WLP: contract pricing; rebates; admin fees; and marketing fees. BMS Ex. 2 (Marre Dep. at 78-79). If provided, all forms of discounts would always appear in a contract, were ***not*** made public by BMS or any publication, and would ***not*** be reflected in the WLP. *Id*. at 82-84.

BMS was successful in signing contracts with most of the large hospitals in the country. *Id.* at 35-36. BMS targeted the larger organizations, with sales volume being the primary determinant. *Id*. at 27. Marre confirmed that contract pricing is ***always*** less than WLP, and that contract prices are confidential and not publicly available. *Id*. at 37-38, 82-84; *see also* Answer ¶ 192 (BMS admits "that certain price discounts it gives to customers are confidential competitive information . . . .") (Dkt. No. 800).

As just a small sampling of relevant documents demonstrates, these confidential discounts, which were purposely not reflected in BMS's WLPs or AWPs, were frequently huge. For example, in an email dated January 10, 2003, Michelle Barnard reported "[redacted]" for the third and fourth quarters of 2002. The weighted average discount off WLP ranged from 61% to 66%. BMS Ex. 53 ([redacted]). *See also* BMS Ex. 43 ([redacted] (lists contract sales prices for Taxol for each quarter of 2002 and chargebacks for Vepesid injection for the same time period. The discounts off of WLP for Taxol are huge – as high as 80% for one customer in the fourth quarter of 2002. [redacted])); BMS Ex. 44 ([redacted] (Consorta proposal showing huge discounts off of WLP for various lawsuit drugs); BMS Ex. 45 ([redacted] (more of the same)); BMS Ex. 46 ([redacted] (Owen Healthcare bid showing huge discounts off of WLP for various lawsuit drugs)); BMS Ex. 47 ([redacted] and [redacted] (Premier Current Contracts summary showing huge discounts off of WLP for various Subject Drugs)); BMS Ex. 48 ([redacted] (MHA Bid spreadsheet showing huge discounts off of WLP ***and AWP*** for various Subject Drugs)).

BMS knew the impact that creating spreads would have: a growing disparity between WLP and AWP creates an incentive for physicians to select the brand. For example, BMS once explained with respect to its Vepesid drug:

[redacted]

[redacted]

BMS Ex. 50 ([redacted]). In order to promote Etopophos, a new BMS drug that was expected to cannabilize BMS's VePesid sales, the document suggested lowering VePesid's AWP in order to create sales for Etopophos: the "[redacted]" *Id.* Furthermore, "[redacted]" BMS Ex. 22 ([redacted]) and BMS Ex. 3 (Kaszuba Dep. at 117-20).

Other documents reinforce BMS's recognition that it could manipulate spreads:

- "[redacted]" BMS Ex. 45 ([redacted]). In the preceding pages of this exhibit, Kaszuba communicates the new WLP to publishers and PBMs (*see* 597-606). Kaszuba testified that no one would have paid AWP for this particular drug at this particular time because they would not have even paid the list price for the drug. BMS Ex. 3 (Kaszuba Dep. at 65).
- "[redacted]" BMS Ex. 52 ([redacted]); BMS Ex. 3 (Kaszuba Dep. at 70-72). *See also* BMS Ex. 3 (Kaszuba Dep. at 79 and 77-78: "[redacted]") Page 102 and Kaszuba Dep. at 78-79: "[redacted]

[redacted]"

c. Individual brand and price histories reveal BMS's manipulation of spreads

Christof Marre, BMS's former Director of Marketing for Oncology, testified to the sales histories of the BMS oncology drugs at issue in the case, providing information about when each drug was first marketed, if and when it lost exclusivity, and his recollections of price trends over time. This testimony, coupled with Dr. Hartman's calculation of BMS spreads, demonstrates that BMS manipulated the spreads on its Subject Drugs.

(1) Blenoxane

Blenoxane is an antineoplastic used in the treatment of various forms of cancer and has several competitors. BMS Ex. 2 (Marre Dep. at 88). Blenoxane was a multisource drug the entire time that Marre was at BMS, and BMS had no specific marketing programs for it. *Id.* at 84-85. Nonethelss, the WLP for Blenoxane remained constant over time while contract pricing dropped. *Id*. at 86.[29] Weighted average discounts off of WLP for 15 and 30 mg formulations of Blenoxane ranged from 62 to 66% at the end of 2002. BMS Ex. 53 ([redacted]; authenticated in Marre deposition as Exhibt 17). In 2002 Duke received contract prices for Blenoxane that were 71% off WLP. BMS Ex. 2 (Marre Dep. at 144); BMS Ex. 54 ([redacted]). BMS Ex. 167 lists Blenoxane contract sales for the third and fourth quarters of 2002 to various hospitals; some discounts were as high as 80%. BMS Ex. 55 ([redacted]); *see also* BMS Ex. 2 (Marre Dep. at 145-46). BMS Ex. 56, Attachment G.2.c to the Declaration of

[29] Marre testified that WLP for generics generally remain constant over time even if actual contract prices fall: "[redacted]" BMS Ex. 2 (Marre Dep. at 86).

Raymond S. Hartman in Support of Plaintiffs' Claims of Liability ("Hartman Decl.") echoes this data, demonstrating that Blenoxane spreads largely increased over time, with spreads on [redacted].

(2) Cytoxan

Cytoxan is the BMS brand name for cyclophosphamide, BMS Ex. 2 (Marre Dep. at 88), and it is an antineoplastic used to treat various forms of cancer. Cytoxan was multisource for much of the class period but became single source towards the end of 2002 or beginning of 2003 when both competitors exited the market. *Id*. at 88-89. BMS had no specific marketing programs for Cytoxan other than the standard contracting practice. *Id*. at 91. For most NDCs, Cytoxan's WLPs remained constant over time, while spreads for most NDCs increased and then decreased in 2001 as the drug was poised to become single source. BMS Ex. 56 (Hartman Decl. Attach. G.2.c). Indeed, after Marre recognized that Cytoxan was once again a sole source drug, he tried to raise contract prices. BMS Ex. 2 (Marre Dep. at 90).

(3) VePesid

VePesid is the BMS brand name for etoposide, *id*. at 91, which is an antineoplastic used to treat cancer of the testicles and certain types of lung cancer. The injectible version was already a multisource drug when Marre started at BMS, *id*., and had numerous competitors. *Id*. at 97. BMS had no specific marketing programs for VePesid other than the standard contracting practice. *Id*. at 91. For most versions of Vepesid, WLPs and therefore AWPs remained constant over time, BMS Ex. 57 (Hartman Decl. Attach. G.2.b), while spreads ballooned in the late 1990s to over 1,000% for several NDCs. BMS Ex. 56 (Hartman Decl. Attach. G.2.c). In 2002 Duke received contract prices for VePesid that were 94-95% off WLP. BMS Ex. 54 ([redacted]); *see also* BMS Ex. 2 (Marre Dep. at 144). Indeed,

pricing "had deteriorated very massively compared to other generic drugs" such that BMS was not always willing to continue matching lower pricing requests from customers. BMS Ex. 2 (Marre Dep. at 93-94). BMS ultimately discontinued some formulations because they were not profitable. *Id*. at 94.

Marre also testified that most of BMS's sales of injectible VePesid in 2002 were made under contracts, BMS Ex. 58 ([redacted]; BMS Ex. 2 (Marre Dep. at 130-31), which, of course, means that no one paid WLP let alone AWP for the drug.

(4) Etopophos

Etopophos is an antineoplastic used to treat cancer of the testicles and certain types of lung cancer, is considered an exclusive drug without generic competition. BMS Ex. 2 (Marre Dep. at 96). BMS had no specific marketing programs for Etopophos. BMS may have considered contracting for some accounts, but discounting was unlikely since it had no competition and was not a large brand. *Id*. at 96-97. WLP remained constant over time, BMS Ex. 57 (Hartman Decl. Attach. G.2.b), as did spreads (for the most part). BMS Ex. 56 (Hartman Decl. Attach. G.2.c).

(5) Rubex

Rubex was a multisource antineoplastic used to treat various forms of cancer. WLPs and AWPs remained constant over time, BMS Ex. 57 (Hartman Decl. Attach. G.2.b), while spreads blossomed in the mid-to-late 1990s and then decreased, BMS Ex. 56 (Hartman Decl. Attach. G.2.c), as BMS phased out the drug. BMS Ex. 2 (Marre Dep. at 97-98).

(6) Taxol

Taxol is the BMS brand name for paclitaxel, BMS Ex. 2 (Marre Dep. at 100), and it was the first of a class of agents called taxanes that interrupt the cell cycle of a cancer cell growth

stage and make the tumor more susceptible to the effects of radiation. It is used to treat ovarian, breast and lung tumors. BMS Ex. 39 (Soule Dep. at 34).

In 2000, BMS dominated the U.S. oncology drug market, accounting for over $1.2 billion of the market's $4 billion in sales. Taxol was the oncology drug leader, with $805 million in sales, with BMS's Paraplatin second at $418 million. BMS Ex. 59 (Christof Marre, "[redacted]" [redacted]). Sixty percent of Paraplatin usage was in combination with Taxol. *Id.* at 000071267. At this time, 69% of the market was represented by office-based oncologists ("OBO"), with hospitals comprising the other 31% of the market. [redacted] OTN had 60% of the OBO market. *Id.*

Taxol lost exclusivity in 2000. Ivax's generic product, Onxol, entered the market in October 2000. Mylan began producing generic paclitaxel in July 2001, and Bedford entered the market shortly thereafter. *See* BMS Ex. 60 ([redacted]); *see also* BMS Ex. 2 (Marre Dep. at 100 (discussing entrance of Ivax, Bedford, Mylan and also Abbott)). Taxotere could be seen as a therapeutic substitution for paclitaxel, but it was a different chemical formulation called docetaxel. *Id*. at 100.

As a result, during this period of generic introduction, Taxol sales through OTN declined significantly from about $23,000,000 per month in January 2001 to $15,000,000 per month by November 2001. BMS Ex. 60 ([redacted]).[30] BMS Ex. 59 at page [redacted] graphs the loss in market share that Taxol experienced as of January 2003.

The WLP for Taxol remained constant over time, and then, after loss of exclusivity, contract prices rapidly decreased. BMS Ex. 2 (Marre Dep. at 100-01); BMS Exs. 56 and 62

[30] By August 2001, OTN lost 50% of its volume of Taxol sales since generic introduction. BMS Ex. 61 ([redacted]).

(Hartman Decl. Attach. G.2.c and G.2.d). Spreads on some NDCs of Taxol exploded from about 25% to over 500% in 2002, BMS Ex. 56 (Hartman Decl. Attach. G.2.c), and the Taxol unit-weighted average spread percentage across all NDCs jumped nearly 100% between 2001 and 2002. BMS Ex. 63 (Hartman Decl. Attach. H.2). As an additional example of patent spread manipulation for Taxol, in 2002 Duke received contract prices for Taxol that were 75% off WLP. BMS Ex. 54 ([redacted]; *see also* BMS Ex. 2 (Marre Dep. at 144).

(7) Paraplatin

Paraplatin treats a wide variety of cancers and is frequently used in conjunction with Taxol. BMS Ex. 39 (Soule Dep at 35). Paraplatin lost exclusivity in November of 2004. BMS Ex. 2 (Marre Dep. at 126). Paraplatin list prices increased over time, BMS Ex. 56 (Hartman Decl. Attach. G.2.c), while spreads remained relatively constant until increasing modestly beginning 2002. BMS Ex. 56 (Hartman Decl. Attach. G.2.c). To address the loss of exclusivity, BMS charted a new course and created a "[redacted]" generic for Paraplatin called "[redacted]" so that BMS could sell a generic version of drug in addition to a brand. Pricing of the generic would follow the pricing of other generic manufacturers, and pricing of the brand would be at a premium over all generics. BMS Ex. 2 (Marre Dep. at 125-29).

d. BMS actively marketed the spread between actual acquisition cost and AWP in order to take advantage of the importance that prescribers place on drug reimbursements

Finally, not only did BMS create and manipulate spreads on its Subject Drugs, it also marketed the spread to customers. A prime exhibit in this regard is provided by the OTN on-line reports discussed earlier. To reiterate, OTN published the "[redacted]" which contained a list of current AWPs for drugs that the client has previously purchased; and (ii) the "AWP/Price

Report," which contained the AWP for drugs that the client purchases, and the billing unit for each particular drug. OTN obtained the AWPs for both reports from the Red Book. ***The report also shows OTN's dispensing unit price in one column and AWP less _% in the next column; customers can input the discount from AWP manually in a setup screen.*** Marsha Peterson, OTN's Western Sales Manager, testified that customers found the price and AWP info displayed on a single screen "[redacted]" and acknowledged that "[redacted]" or "[redacted]" are relevant to the customers. BMS Ex. 6 (Peterson Dep.); *see also* BMS Ex. 64 (Peterson deposition Exhibit 6). OTN Vice President of Government Relations and Managed Care Services John Akscin also testified that practices found the presentation of the information in the AWP Price Report to be "[redacted]" BMS Ex. 4 (Acksin Dep. at 112).

OTN also offered customers a "[redacted]" report that displayed, by regimen, the AWP, acquisition cost and "[redacted]" or spread. BMS Ex. 65 ([redacted]).

BMS also provided its sales representatives with spread marketing materials, or they created their own. For instance, some John Akscin Powerpoint presentations included information on the difference between the acquisition cost and Medicare reimbursement amounts for oncology drugs. *See, e.g.*, BMS Ex. 35 ([redacted]; BMS Ex. 4 (Akscin Dep. at 94-95). In a document that appears to have been distributed to the sales force, BMS compared spreads on Taxol with spreads on Taxotere. Taxol generated a 35.5% "margin" between Medicare reimbursement and OTN cost, while the same metrics for Taxotere produced a smaller margin of 12.7%. BMS Ex. 66 ([redacted]). A similar analysis for weekly administration generated a 52% margin for Taxol compared to a 23% margin for Taxotere. *Id.* at

[redacted]. Taxol also won out on a three-week administration period, with a 39% margin versus 23% for Taxotere. [redacted]

BMS distributed to the sales force a Powerpoint comparing costs and reimbursement amounts for Taxol and Paraplatin purchased from OTN. BMS Ex. 67 ("[redacted]"

[redacted]

The BMS sales force translated these spread marketing signals from management into action and marketed the spread. For example, BMS "[redacted]" Sales Representative Doug Soule admitted to having discussions with clients about "[redacted]" the term that he uses to refer to the difference between what a customer pays and is reimbursed for a BMS drug. BMS Ex. 39 (Soule Dep. at 55). As Soule testified, "[redacted]"

"[redacted]" was a reference to a competitor's drug. *Id*. at 57. Although he tries to focus on the clinical aspects of the drugs, some clients focus more on reimbursement issues and financial aspects. *Id*. at 58-59. Soule testified that there is "[redacted]" including Taxol, *id*. at 109, and the company has over time provided Doug with cost and AWP information. *Id*. at 160-62. He also assumes that competitors discuss margins with their clients for the drugs that they sell. *Id*. at 162. Furthermore, Soule has had discussions with other BMS sales reps about margins. *Id*. at 167-68:

[redacted]

[redacted]

Soule also created a number of documents reflecting spread marketing or other discussions with clients about reimbursement issues. One includes a "[redacted]" where Soule compared spreads between Taxol and Paraplatin. *See* BMS Ex. 68.

Documents produced by sales representative Barbara Davidson, another "[redacted]" also reveal spread marketing. *See* Ex. 69:

[redacted]

- [redacted]"

These are just a few of many examples.

3. There is No Genuine Issue of Material Fact that GSK's AWPs Neither Reflected an Average nor Met OIG Guidelines, and that GSK Purposefully Manipulated And Marketed Spreads

GSK consistently set prices for its physician administered products for the purpose of increasing AWP. Neither its wholesale list prices nor the associated AWPs bore any meaningful relationship to the prices paid by physicians for these drugs. A survey of zofran and kytril pricing history proves this.

a. Glaxo's AWPs for Zofran bore no meaningful relationship to prices paid

Glaxo knew from the time of the Zofran launch that the AWP-based reimbursement profit that it could generate for oncology clinics that used Zofran could be a major selling point. Because Zofran faced no competition from a therapeutic equivalent at the time of launch, however, Glaxo did not need to drive market share through its power to set AWP and inflate the spread. As a result, in the absence of competitive pressure, from 1991 to 1994, Glaxo's AWP did bear a meaningful relationship to AWP. It was only in response to the U.S. launch of competing 5HT3 Kytril, in March 1994, that Glaxo began inflating reimbursements through fraudulent price increases in an effort to achieve competitive advantage. These efforts accelerated after a third anti-emtic, Anzemet, came to market in May 1998. As time passed, the relationship between Zofran's AWP and the prices actually paid for the drug became more and more remote.

(1) Zofran initial pricing

Glaxo knew before the Zofran launch that its ability to inflate the spread on Zofran could be used as a selling tool. GSK Ex. 48 ([redacted]). Despite this knowledge, Glaxo also understood that with no therapeutic

equivalent to Zofran on the U.S. market, there was no need to manipulate AWP to inflate the spread. *See* GSK Ex. 49 (Zofran Pricing Strategy) ("[redacted]") (emphasis added). The Zofran launch NWP was set at $165/40mg vial and an AWP of $198, yielding a Zofran ASP/AWP spread in 1991 was 20.2%.

Glaxo increased the wholesale price and AWP for Zofran in September 1992, GSK Ex. 50 ([redacted]), but its actual prices moved in tandem. The Zofran NWP as of 9/28/92 was $172.92/40mg vial, yielding an AWP of $207.50, yielding an ASP/AWP spread in 1992 of 21.9% and in 1993 of 21.1%.

(2) Zofran pricing in response to Kytril's competitive threat

With the introduction of Kytril, Zofran's AWP and ASP diverged. Glaxo monitored Kytril's progress through the regulatory approval process and expected Kytril to be available in the U.S. market late 1Q94. Glaxo expected Kytril to have "[redacted]" – in other words, therapeutic equivalence. GSK Ex. 51 ([redacted]). In response to the anticipated competitive threat, Glaxo embarked on a pricing strategy that combined an AWP increase with "[redacted]" through contracting prior to the price increase. The specific mechanism for this spread inflation was to "[redacted]" in order to "[redacted]" GSK Ex. 52 ([redacted]). *See also* GSK Ex. 53 ([redacted]

[redacted] explaining purpose of price increase to provide "[redacted]

[redacted]").

Pelzel testified that the January 1994 price change was structured to increase the spread on Zofran in response to the launch of Kytril:

[redacted]

GSK Ex. 12 (Pelzel Dep. at 190).

Pelzel elaborated on this rationale later in his deposition:

[redacted]

Id. at 195 (emphasis added).

Effective January 3, 1994, Glaxo increased the NWP of Zofran IV by 3.5% to $178.97/40mg vial yielding an AWP of $214.76. For customers who contracted before the 1/3/94, however, the purchase price would remain at $172.92. Contract pricing, of course, had

no impact on the AWP at which these customers obtained reimbursement, yielding an actual acquisition cost/AWP spread of 26.6%.

Glaxo was taken by surprise by Kytril's market penetration in oncology clinics, and quickly considered an additional price increase to thwart competition – that is to say, increase the AWP, but not the selling price. The price increase proposal drafted by Zofran Product Manager David Cory and submitted after several approvals to the Strategic Pricing Committee was explicitly designed to enlarge the divergence between AWP and actual sale price (GSK Ex.54). Cory offered two alternatives:

[redacted]

Glaxo understood that the proposed AWP increase reflected "[redacted]" and worried about the being revealed as "[redacted]" GSK Ex. 55 ([redacted]). In addition, following the Strategic Pricing Committee meeting on November 4,

1994, additional materials were prepared for division CEO George Morrow. Faced with these concerns, Glaxo restructured the recommended price increase, but nevertheless took it. Effective January 9, 1995, Glaxo increased the NWP for Zofran IV to 194.98/40mg yielding an AWP of $233.01. As a result of wholesaler rebates, Glaxo knew that the actual acquisition cost for clinics would be $172.92/40mg. GSK Ex. 56 ([redacted]).

Glaxo's price increase caught the attention of SKB. In a letter from SKB's lawyer Ursula Bartels to Glaxo's lawyer Timothy Proctor dated February 22, 1995 (GSK Ex. 57), SKB stated characterized accurately Glaxo's method and motive for the price increase:

(3) Further divergence of AWP and actual selling price

In 1996, Glaxo continued its pattern of increasing price to inflate the spread. *See* GSK Ex. 58 ([redacted]) ("[redacted]

[redacted]"). Glaxo's price increase was well-understood by its competition. An internal SKB memo from Kytril marketing to Kytril sales dated March 11, 1996 (GSK Ex. 59) explained that "[redacted]" Effective March 7, 1996, Glaxo increased the NWP for Zofran IV to 203.69/40mg yielding an AWP of $244.43. As a result of wholesaler rebates, the wholesaler cost would remain at $169.07 and the actual acquisition cost for clinics would presumably also remain at $172.92/40mg, yielding and AAC/AWP spread over 40%.

The practice of setting AWPs with no relationship to actual selling costs continued with Glaxo's next Zofran price increase in May 1999. The price manipulation was effective in increasing the disparity between actual selling prices and AWP, because although the increased AWPs worked to increase the Zofran reimbursement rate, the offsetting discounts, chargebacks, and rebates were concealed from the reporting services. As Pelzel testified

[redacted]

GSK Ex. 12 (Pelzel Dep. at 266-67).

The AWPs set for Glaxo products consistently bore no relationship to actual selling prices. They were set purely to enlarge spread and obtain advantage over competitors at the expense of consumers and third-party payors.

b. SKB's AWPs for Zofran bore no meaningful relationship to prices paid

Kytril was the second entry into the 5HT3 market. In the three years that Glaxo had exclusive control of the market, Zofran had become the gold standard for antiemetic treatment. SKB knew that as a therapeutically equivalent competitor to Zofran, Kytril would have to be differentiated on the profit its purchase could offer to oncology clinics. SKB set meaningless AWPs for Kytril, just as Glaxo did for Zofran, for competitive purposes.

(1) Kytril initial pricing

The launch price for Kytril was established to compete with Zofran in the oncology clinic market on spread. To exceed Zofran's spread, however, rather than create arbitrary divergence, SKB established a WAC to AWP ratio for Kytril of 25%, exceeding the analogous ratio for Zofran of 20%. *See* GSK Ex. 60 ([redacted]).

The greater ratio, however, proved insufficient to meet SKB's competitive needs. As a result, SKB offered chargebacks to wholesalers, the benefit of which was passed on to oncology clinics, yielding an initial purchase price was around $120. This, from the outset, SKB cut Kytril pricing from its AWP moorings.

(2) Setting AWP in response to further competitive pressures

In March 1996, SKB raised the AWP of Kytril. This was in direct response to, and the same percentage as, Glaxo's price increase for Zofran. This price increase, however, further unhinged Kytril's selling price from AWP. [redacted] (GSK Ex. 61), shows SKB's acknowledgement of the absence of relationship between AWP and cost:

In late March 1996, the WAC for the 1 mg vial of Kytril was raised 4.8% to $139.16, and the AWP was raised to $173.95. The average purchase price, however, was about $122, yielding a spread of about $51.49, about 37%. Thus, by March 1996, the AWP for Kytril bore effectively no relationship to the price paid by oncology clinics.

(3) Further divergence of AWP and actual selling price

In November 1998, SKB, again increased the price of Kytril, this time by 4.5%. The rationale for the price increase is set forth in a memorandum from Rich Francovitch, Kytril Brand Leader, to Kevin Lokay, VP for Marketing and Sales of Oncology Products, dated

October 15, 1998 (GSK Ex. 62). The data in the recommendation shows the minimal impact to revenues from the price increase as follows:

[redacted]

The table shows that the purported price increase created greater divergence between AWP and actual purchase prices because the price increase would be almost completely absorbed by RAR (*i.e.*, rebates). Since the acquisition cost to a majority of Kytril's customers would remain at the contracted amount, SKB knew that it was not raising actual sale prices, but only spread. Francovitch explained this rationale in his deposition:

[redacted]

GSK Ex. 104 (Francovitch Dep. at 39).

Francovitch further explained this rationale:

[redacted]

Id. at 43-44.

Francovitch also included a comparison of Kytril, Anzemet and Zofran's AWP, WAC and Onc Supply prices in his 1998 Recommendation, which further shows SKB's price increase strategy was created AWPs with no relationship to actual prices:

[redacted]

In 1999, SKB continued its pattern of increasing Kytril's WAC/AWP without regard to actual process. In April 1999, despite a Kytril price increase just six months earlier, Kevin Lokay, SKB VP for Sales and Marketing of Oncology Products, directed Pearl Pugh, Kytril Product Manager, to recommend another Kytril AWP increase. Pugh submitted a price increase recommendation dated April 23, 1999 ("1999 Recommendation") (GSK Ex. 63), which Lokay approved (GSK Ex. 64). The price increase was made effective May 18, 1999. GSK Ex. 65.

The 1999 Recommendation demonstrates that the price increase had no relationship to actual price or cost. SKB carefully monitored competitor spreads and set them forth expressly as a basis for recommending price increase. GSK Ex. 30 (Pugh Dep. at 81). The table attached to the 1999 Recommendation shows that SKB focused on spreads by including Kytril's and its competitors' AWP, WAC, and Onc Supply amounts from which SKB knew reimbursement amounts could be calculated. The above-mentioned comparative prices table (relevant portion) as follows:

[redacted]

Upon receiving Lokay's request for a Kytril price increase recommendation, Pugh only contacted the finance department and only reviewed Kytril's price history and sales impact data (*i.e.* price and RAR). She did not consider ingredient costs, manufacturing costs, or other costs of production or doing business. GSK Ex. 30 (Pugh Dep. at 38-40).

The 1999 Kytril price increase did not enhance revenue. SKB knew that "[redacted]" the impact on revenues would be insignificant. GSK Ex. 50. This concept was explained by Lokay in his deposition as follows:

[redacted]

SKB knew that the 1999 Kytril price increase would increase Kytril's AWP but not the clinic purchase price which would in turn increase the spread between a clinic's actual acquisition cost and reimbursement amount. Pugh explained further in her deposition:

[redacted]

GSK Ex. 30 (Pugh Dep. at 84).

* * *

[redacted]

Id. at 87-88.

Ultimately, SKB capitalized on its abandonment of relationship between AWP and purchase price, communicating to its sales force in a chart the new Kytril AWP, WAC, Oncology Supplier price and contract price range compared with its competitors, a week after the change went into effect. GSK Ex. 66 ([redacted]).

The AWPs set for SKB products consistently bore no relationship to actual selling prices. They were set purely to enlarge spread and obtain advantage over competitors at the expense of consumers and third-party payors.

c. Glaxo marketed the spread

Glaxo sales representatives routinely used the AWP information supplied to them by Zofran marketing personnel when making sales calls. Medicare reimbursement and Zofran spread information were components of the oncology representative training provided by the company to sales representatives. The AWP and acquisition cost information provided to sales representatives at training was routinely updated through communications from Zofran product managers and regularly-held national and regional meetings. Even though Glaxo maintains that it had an express policy against "marketing the spread," memoranda, communications, and the call notes maintained by sales representatives show that the AWP and spread information supplied to the sales organization were actively used in selling Zofran.

In November 1996, Brian Coffey, an oncology sales representative for Glaxo, wrote a letter to Jim Carrier, the executive director of American Oncology Resources ("AOR"), as a follow-up to a meeting Coffey and Carrier had "concerning issues on reimbursement with antiemetics." GSK Ex. 67 [redacted]. The letter had been sent to Dean Giovaniello and Ron Sorrentino, Zofran product managers the time. According to Dean Giovaniello, a Zofran product manager in 1996, AOR was a "[redacted]" which together were "[redacted]" GSK Ex. 103 (Giovaniello Dep. at 165). In the letter, Coffey summarized his discussion with AOR, writing that Zofran and Kytril were interchangeable when considering efficacy:

[redacted]

Coffey immediately distinguished Zofran, however, on the basis of reimbursement spread:

[redacted]

Coffey included in his letter the sales message conveyed to AOR clinics by Glaxo sales representatives:

[redacted]

Included with Coffey's letter to AOR was a copy of an AOR interoffice memo dated May 10, 1996. GSK Ex. 67 at [redacted]. The memo, which states that "[redacted]" has a section of text that has been blacked out. *Id.* In his letter, Coffey wrote that he assumed the blacked out text "[redacted]" [redacted] Coffey's comment indicates his subjective understanding that oncology clinics, and in this case AOR, were interested in cost and reimbursement comparisons of Zofran and its competitors.

When questioned about Coffey's letter, Dean Giovaniello indicated that he would have had concerns with Coffey's letter, although he did not recall communicating any concerns:

[redacted]

[GSK Ex. 103 (Giovaniello Dep. at 166).]

Giovaniello did testify to his concerns over Coffey's letter:

[redacted]

[redacted]

[*Id.* at 166-67.]

In his testimony, however, Giovaniello did not express concern over Coffey's statements regarding the profitability of Zofran reimbursement or the fact that the reimbursement message was communicated to each of AOR's accounts.

In May 1998, Michele Adams, a district manager and former oncology sales representative, received from one of her sales representatives, Paul Ostruszka, an email showing that he had used AWP information in the sale of Zofran. The email was forwarded to David Robinson, a regional VP of sales at the time, and Peter Kaylid, Director of Marketing for Oncology Products. GSK Ex. 96 (Robinson Dep. at 19).

In the email, Ostruszka referenced a "[redacted]" GSK Ex. 68 at [redacted]. The pricing comparisons show the AWP, acquisition cost, Medicare reimbursement and "[redacted]" for forms of Zofran, Kytril and Anzemet. *Id.* at [redacted]. Ostruszka also wrote to Adams: "[redacted]" *Id.* at [redacted]. The email confirms, therefore, that Ostruszka used AWP and reimbursement profit information in selling Zofran to oncology clinics. Moreover, Ostruzska included in his email the selling points that he used to overcome the three dollar difference in reimbursement between Zofran and Anzemet. *Id.*

Even though Robinson testified in his deposition that the use of materials like the comparison chart was against company policy, he could not recall taking any action to stop the use of the chart. GSK Ex. 96 (Robinson Dep. 178-83).

In February 1995, in-house counsel at SmithKline Beecham sent a letter to counsel for Glaxo regarding Glaxo's marketing practices for Zofran. In the letter, SKB's counsel cited the January 1995 Zofran price increase as an effort to increase the reimbursement profit available to physicians. GSK Ex. 69 at [redacted]. Attached to the letter was an "[redacted]" GSK Ex. 67 at [redacted]. The homemade sheet shows Zofran and Kytril AWPs and contract prices in a way that would allow easy comparison of reimbursement spreads.

A 1998 email from Jim Gueno, a regional sales manager, provides an example of a Glaxo oncology sales representative using AWP and spread information in the sale of Zofran. In his email to Ron Sorrentino and David Robinson, Gueno wrote that Oncology Network of America ("[redacted]") could give 100% market share to the "[redacted]" in other words, antiemetic providing the greatest reimbursement profit. Gueno provided the reimbursement profit numbers for Kytril and Anzemet, based on the acquisition costs quoted to ONA. GSK Ex. 70 at [redacted]. Gueno wrote that if they could use a performance contract to lower the acquisition cost, "[redacted]" *Id.* Gueno testified that he had hoped to win the business by providing the best reimbursement profit:

[redacted]

[GSK Ex. 105 (Gueno Dep. at 157-60).]

The last page of GSK Ex. 70 indicates that the ONA contract was signed in September of 1998. GSK Ex. 71 ; GSK Ex. 105 (Gueno Dep. at 160-61).

A monthly report from Jim Gueno also shows that GW sales representatives marketed and sold Zofran with reference to reimbursement profit. In reference to an oncology clinic using Kytril at that time, Gueno wrote:

In his deposition, Gueno testified about the "":

[redacted]

[GSK Ex. 105 (Gueno Dep. at 174-75).]

Gueno's monthly report also indicates that another sales representative countered a Kytril contract offer from SKB with information that reimbursement for Zofran is better:

[redacted] [GSK Ex. 71 at [redacted].]

The sales call notes of Scott Obenshain, a Glaxo sales representative, indicate that he communicated AWP to oncology clinics in his efforts to sell Zofran. In notes memorializing his contact with the Buffalo Medical Group, an oncology clinic, he described discussions on Zofran's AWP, contract price and spread. Obenshain testified that he knew that offering lower contract prices to Buffalo Medical Group would increase the reimbursement spread the clinic received:

[redacted]

[GSK Ex. 99 (Obenshain Dep. at 180).]

In a note dated May 19, 1999, Obenshain wrote "[redacted]" GSK Ex. 72. Regarding this particular call note, Obenshain testified as follows:

[redacted]

[GSK Ex. 99 (Obenshain Dep. at 186).]

In August 1999, Obenshain wrote that he "[redacted]" GSK Ex. 72 at date 1999-08-04.

Another set of call notes from Scott Obenshain shows that he was comparing the reimbursement spread with that of Anzemet. GSK Ex. 73.

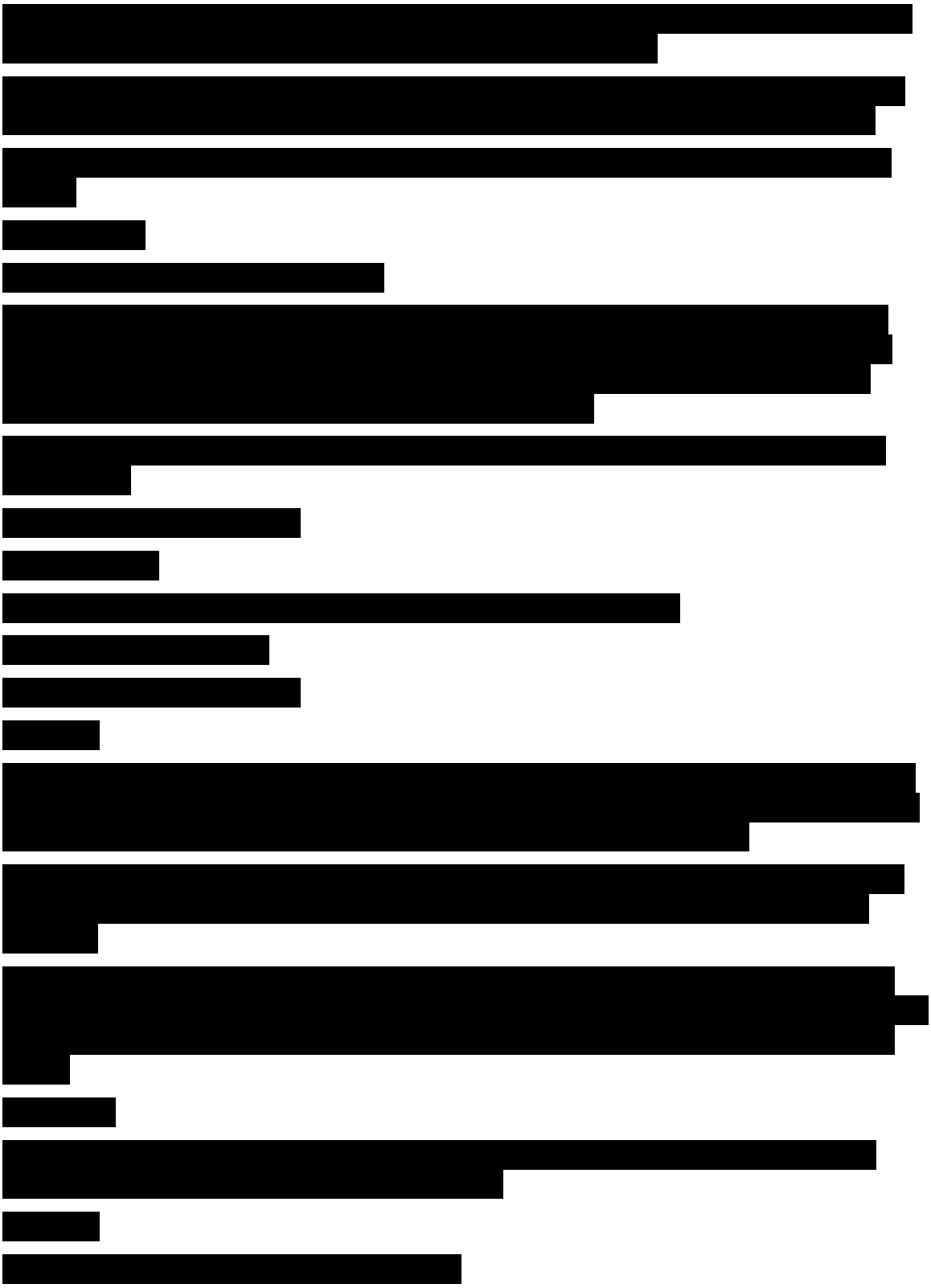
[redacted]

[redacted]

[GSK Ex. 99 (Obenshain Dep. at 272-74).]

Noreen Kaim, a Glaxo oncology sales representative, also used AWP and spread information in selling Zofran. Only a few examples of Kaim's use of AWP and spread information are included here. Kaim testified that she regularly kept her call notes in conformity with company policy and that the notes reflect what occurred during her sales calls. GSK Ex. 101 (Kaim Dep. at 198-203). In one call note, Kaim wrote that the account was "[redacted]" GSK Ex. 74 at 001. In the very next call note, Kaim wrote about the account telling her that Anzemet provided a greater spread because of an acquisition cost decrease. In response, Kaim stated that she "[redacted]" *Id.* at 002. Regarding that statement, Kaim testified as follows:

[redacted]



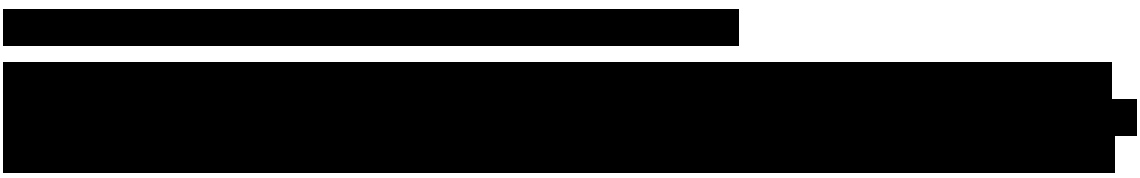
[GSK Ex. 101 (Kaim Dep. at 211-14).]

In general, Kaim's call notes illustrate that she regularly discussed AWP and spread information with the oncology clinics in her sales territory.

Annette Schautz, a Glaxo oncology sales representative working in western Michigan, also recorded a number of sales call notes that indicate her use of AWP and spread information. Schautz testified that she regularly kept her call notes pursuant to company policy and instruction. GSK Ex. 95 (Schautz Dep. at 131-35). Schautz testified that she knew of physicians who were interested in the profit provided by reimbursement. *Id*. at 62. Schautz also testified that she recalled comparing the reimbursement spread provided by Zofran with the spread provided by other drugs:

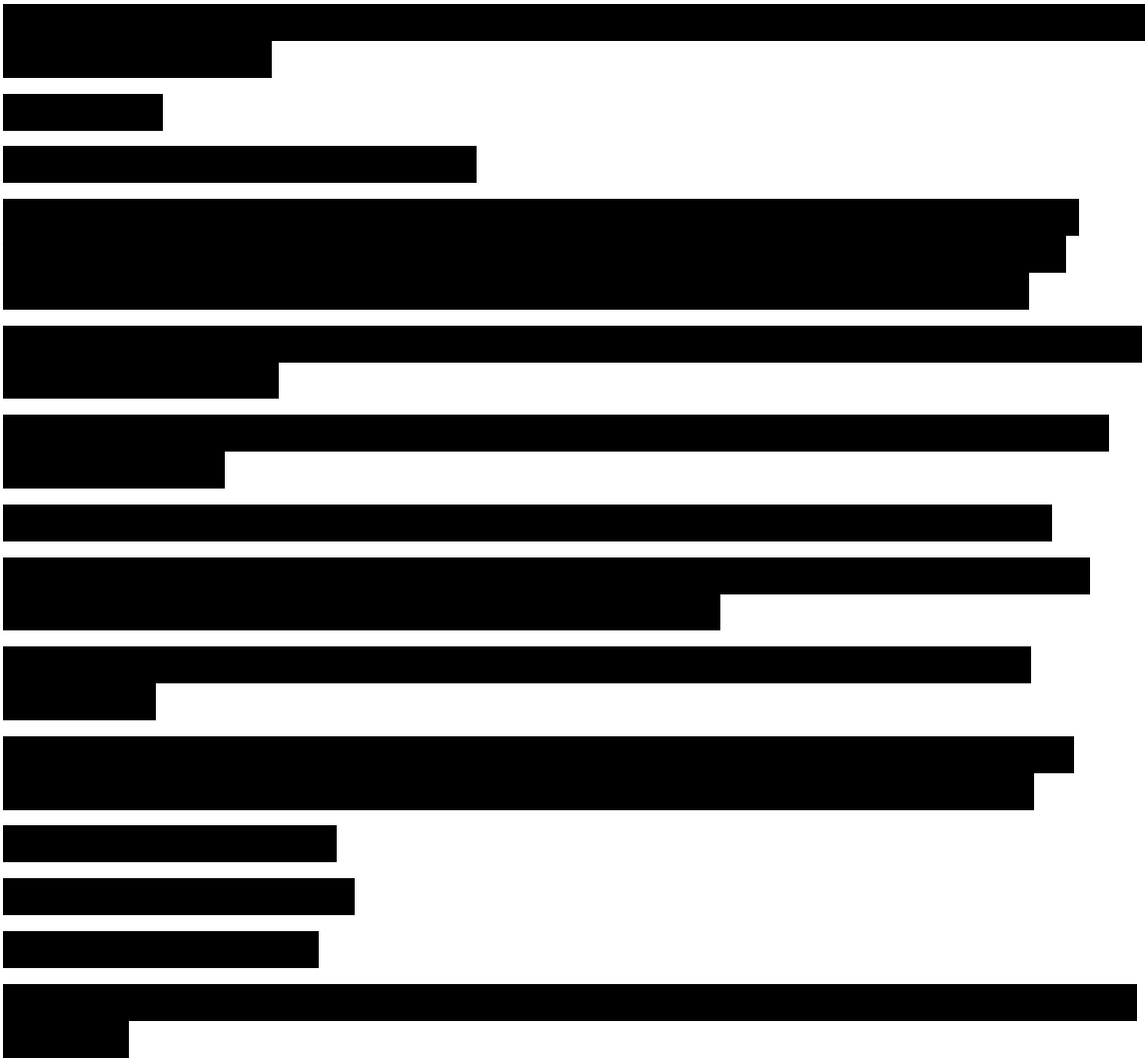
[*Id.* at 67.]

Schautz also included a spread calculation in at least one of her call notes:



[*Id*. at 69-70.]

Schautz further testified that she understood that a lower acquisition price would increase the reimbursement spread:



[*Id*. at 75-77.]

d. SKB marketed the spread

SKB purported to have a "policy" against marketing based on AWP and the spread. But the policy was undefined, unwritten, and unenforced. Indeed, SKB actually permitted the Kytril sales force to openly discuss such issues with clinics and use "spreadsheets" designed to enable the sales team to illustrate for customers how Kytril compared to its competitors in terms of profitability.

(1) SKB's overall sales strategy was to promote Kytril based on spread

From the time SKB launched Kytril in March 1994, it positioned the drug in the clinical market as being therapeutically equivalent to Zofran, but offering the clinic customer better profit. To capture market share away from Glaxo, SKB seized upon the profit available to physicians through the Medicare Part B reimbursement system as a marketing strategy. SKB

promoted Kytril by highlighting the profit clinics could obtain through the difference between the AWP and actual acquisition cost of Kytril, and by emphasizing that Kytril was more attractive than Zofran in terms of the spread.

Kytril Sales Director Mark Levonyak acknowledged that, with the exception of a brief period, spread issues could be and were discussed openly with customers. He stated that during the initial period, "[redacted]" GSK Ex. 100 (Levonyak Dep. at 80-81). Levonyak admitted that during this period, the sales force used spreadsheets showing the comparative spreads of Kytril and its competitors and had comparative spread discussions with physicians. *Id*. at 91-93, 214-17.

Levonyak stated that there was then a "[redacted]" in which all spread discussions and documents were prohibited. *Id*. at 81. This new policy then "[redacted]" and spread discussions with physicians were once again permitted "[redacted]" and spread documents were once again permitted so long as the sales representatives did not actually "[redacted]" *Id*. at 81-85, 126, 214-18. The period in which spread discussions and documents were prohibited lasted only three to four months sometime in 1997, until the "[redacted]" including "[redacted]" clarified what the change in policy meant. *Id*. at 82-85, 97. After that three to four month period, SKB continued to sell based on spread, although the discussion had to be more nuanced. As Levonyak explained:

[redacted]

Id. at 217-19.

Sales representative Richard Panian acknowledged that there were discussions with customers about how the spread of Kytril compared with the spread of Zofran. GSK Ex. (Panian Dep. at 38-39). He stated that spreadsheet information could be used by the sales force to respond to questions from customers. *Id*. at 200-02. Panian also acknowledged that if SKB gave a better price for Kytril to a customer, it would enable Kytril to better compete based on spread. *Id*. at 40-41. He acknowledged the same regarding Anzemet; SKB tried to compete with Anzemet's better spread by reducing the price of Kytril. *Id*. at 41-42. Panian also stated that spreadsheets comparing the price, AWP, and spread of Kytril and its competitors were circulated among the sales force, which enabled sales representatives to respond to questions from clinics regarding such information. *Id*. at 93-95.

Sales representative Jim Pinter acknowledged that reimbursement was important to physicians because "[redacted]" GSK Ex. 97 (Pinter Dep. at 43-44). He stated that the environment in which he sold Kytril was different from his previous experience selling pharmaceuticals because "[redacted]"; rather, the focus was more on "[redacted]" *Id*. at 83-85. Pinter explained that discussions with customers about comparative reimbursement issues had to be "[redacted]" adding: "[redacted]" *Id*. at 107-08; *see also id*. at 134. Pinter testified that although he could not directly mention spread, what he "[redacted]

[redacted]" *Id*. at 186-87. In any event, he acknowledged that receiving spreadsheets from within the company "[redacted]"; he understood they were intended to be "[redacted]" *Id*. at 113-15. When asked about a June 1997 spreadsheet, Pinter responded: "[redacted]" *Id*. at 159-61.

(2) Increased competition drove increased marketing based on spread

Before the launch of Anzemet, SKB's sales effort was focused on promoting Kytril as a more attractive antiemetic product than Zofran based on Kytril's more favorable spread. For example, an email from Sales Director Mark Levonyak to his sales force dated June 12, 1997 attached a spreadsheet that compares the WACs, AWPs, and spreads of Kytril and Zofran. GSK Ex. 75 (Levonyak Exh. 11). Levonyak's email states: "[redacted]" Levonyak acknowledged that this spreadsheet was intended to be manipulated by the sales representatives to allow them to see the comparative spreads of Kytril and its competitors for each account. GSK Ex. 100 (Levonyak Dep. at 221-24). The spreadsheet ([redacted]) shows that Kytril could make more profit for physicians than Zofran.

Glaxo responded to the increased spread competition from Kytril, and especially the Kytril MDV, by launching a Zofran 32mg pre-mixed bag. This product contained the same amount of medicine at 32mg of Zofran from a vial, but was priced in a way to provide a greater

spread (higher AWP + greater contractual rebates = greater spread). When Anzemet came on the market, SKB (as well as Glaxo) was presented with yet another new competitive threat in terms of spread. Due to HMR's strategy to position Anzemet as offering even greater profitability than either Kytril or Zofran, the competition intensified among the three antiemetic manufacturers in terms of which product could offer physicians the greatest spread. As the Kytril 2000 Tactical Plan confirmed, "[redacted]" GSK Ex. 76 (Levonyak Exh. 1, at p. 0118006). The Kytril 1999 Situation Analysis acknowledged, "[redacted]" GSK Ex. 77 (Kissel Exh. 14 at [redacted]). This spread-based competition manifested itself in the selling tactics used by the SKB sales force.

Although Kytril could not always offer a greater spread to clinics than Anzemet (or Zofran), SKB's sales strategy continued to be to compete as best it could on spread. A spreadsheet circulated by Levonyak to his sales force dated February 12, 1998 compares the WACs, AWPs, and spreads of Kytril, Zofran, and Anzemet. GSK Ex. 78 (Levonyak Ex. 15). This spreadsheet shows that at Kytril's average dosage of .7mg, Kytril's spread was $8.83 lower than the Zofran bag, $1.03 lower than the Zofran vial, and $20.01 lower than Anzemet; but that at a 1mg dosage of Kytril, Kytril's spread was $13.62 greater than the Zofran 32mg bag, $21.42 greater than the Zofran vial, and $2.43 greater than Anzemet.

In a monthly report dated May 21, 1999 from Sales Director Mark Levonyak to his supervisor, Sales Vice President Bill DeVinney, Levonyak reported that two clinics stayed with Kytril instead of switching to Anzemet because "[redacted]" GSK Ex. 79 (Levonyak Exh. 5K). Levonyak acknowledged at his deposition that

he "[redacted]" for these contracts in order to offer the clinics a spread that was close to the spread offered to them by the Anzemet competing bid. GSK Ex. 100 (Levonyak Dep. at 173-78).

SKB raised the price of Kytril twice in six months (11/98 and 5/99) in order to put Kytril back on top of the spread competition. Efforts to promote Kytril based on AWP and spread continued. For example, a April 12, 199 email from a sales representative to Sales Manager Jeffrey Holland requested a Loyalist contract price for an account in order to compete based on spread. The email stated: "[redacted]" GSK Ex. 80 (Holland Ex. 2). Similarly, in a June 14, 1999 email from sales representative James Pinter to Levonyak and forwarded from Levonyak to Kytril Product Manager Pearl Pugh, Pinter requested a Loyalist contract for a "[redacted]" account in order to compete based on spread. The attached memo states: "[redacted]" GSK Ex. 81 (Levonyak Ex. 6).

In July 1999, Glaxo raised the price of Zofran, which again put Kytril at a relative disadvantage to Zofran in terms of spread. This increased the competitive challenge to Kytril, while the spread competition from Anzemet also continued to be fierce. For example, on 8/19/99, sales representative Richard Panian circulated a new manipulable spreadsheet to the other sales representatives in his region. GSK Ex. 82 (Levonyak Exh. 17). This spreadsheet shows that at a contract price of $105 and Kytril's new raised AWP of $195.20, Kytril offered a competitive spread to Zofran and Anzemet at a 1mg dosage (Kytril $80.4; Zofran bag $80.7;

Anzemet $80.1), but offered a lower spread of $56.3 at a .7mg dosage. Moreover, in his 10/99 monthly report to DeVinney, Levonyak reported that an account was considering switching to Anzemet based on reimbursement but the Kytril representative "[redacted]" GSK Ex. 83 (Levonyak Ex. 50).

In January 2000, HMR followed suit and raised the price of Anzemet, which improved its competitive spread position and increased the pressure on SKB to promote Kytril based on spread. In his 4/00 monthly report to DeVinney, Levonyak reported: "[redacted]" GSK Ex. 84 (Levonyak Ex. 5S).

(3) Promotion based on double dipping

In addition to its general promotion of Kytril based on its profitability due to the spread between the acquisition cost and the reimbursement amount, SKB promoted Kytril as being particularly profitable due to a loophole in the Medicare reimbursement system that made it relatively easy to overcharge Medicare for Kytril. Under the initial J-Code (1625) assigned to Kytril, the billing unit was 1mg. This meant that physicians could bill Medicare for a single administration of a full 1mg even though the average dosage was .7mg. Although physicians were supposed to discard the unused portion of the vials for which they had obtained reimbursement, some clinics batched together the remaining portions from several vials (including some overfill that was present in each vial) to create a new dosage and seek reimbursement from Medicare for the administration of that new dosage. This practice, called "double dipping," constituted Medicare fraud since the clinic was billing Medicare twice for the

same product – once when they billed for an administration of a full 1mg vial and again when they billed for a new administration created from the batched remainders from several vials.

The practice of double dipping gave SKB a competitive advantage to Glaxo by providing the opportunity for clinics to increase their profits by using Kytril. But it did so at the expense of Medicare payors and consumers. The Medicare reimbursement structure was based on the assumption that there was a reasonable and constant relationship between WAC and AWP. To the extent double dipping distorted WAC (by not accounting for the free dosages that were reimbursed), it also distorted AWP, and therefore negated the assumptions underlying the reimbursement formula.

SKB was aware that the practice of double dipping was occurring and took advantage of it. The Kytril team knew that the opportunity for double dipping existed, and therefore was aware that it was a possible motivating factor in the clinics' selection of an antiemetic. Richard Van Thiel, a Kytril Product Director, acknowledged that the SDV provided the potential for double dipping, which he called fraud, stating "[redacted]" GSK Ex. 102 (Van Thiel Dep. at 74-75). Sales Director Mark Levonyak also acknowledged the opportunity for double dipping with the SDV, stating: "[redacted]" GSK Ex. 100 (Levonyak Dep. at 198-99). He also acknowledged that he had been aware of "[redacted]" *Id*. at 200. Sales representative Richard Panian also acknowledged the opportunity for double dipping with the SDV, stating: "[redacted]" GSK Ex. 98 (Panian Dep. at 280). He also stated that he "[redacted]" and that he could "[redacted]" *Id*. at 278-79.

Despite stated opposition to encouraging or facilitating double dipping, the sales force created spreadsheets designed to promote Kytril through encouraging double dipping by demonstrating how clinics could reap greater profits through the practice:

* In 1995, a Glaxo sales representative obtained an example of a sales piece that an SKB sales representative had given a customer. This document shows several possible scenarios of Kytril vial usage with the note: "[redacted]" GSK Ex.85 (Marshall Ex. 24).

* [redacted]" from Birdie D'Andrea, Kytril Product Manager, to SKB Priority Consultants (a division of the sales force), Bill DeVinney, V.P. Sales, Richard Van Thiel, Kytril Product Director, Jack Fish, David Pernock, Howard Pien, and others, included a spreadsheet comparing the cost, AWP, and profit of Kytril and Zofran. GSK Ex. 86 (Van Thiel Ex. 7). A note to the spreadsheet states: "[redacted]" Van Thiel acknowledged that the profit figures shown on this spreadsheet could only have been realized through double dipping, stating "[redacted]" GSK Ex. 102 (Van Thiel Dep. at 158-63).

* An email from Sales Director Mark Levonyak to his sales force dated 6/12/97 attached a spreadsheet that shows how physicians can reap a greater profit from double dipping. GSK Ex. 75 (Levonyak Exh. 11). Levonyak acknowledged that this spreadsheet shows that Kytril offered a better spread than Zofran if the customer batched the remainders from SDVs and billed for reimbursement for the extra dosages. GSK Ex. 100 (Levonyak Dep. at 229-30). Sales representative Richard Panian also acknowledged that this spreadsheet shows how physicians could make a greater spread by billing Medicare for the extra dosage they could obtain through batching of the remainders from SDVs. GSK Ex. 98 (Panian Dep. at 193-96). Panian also acknowledged that the spreadsheet shows how clinics could make a greater spread from Kytril than Zofran if they did so, whereas the spread for Kytril would be lower than for Zofran if they did not. *Id*. at 196.

In 1995, SKB began developing a 4mg multi-dose vial (MDV), which afforded clinics an even easier way to double dip than with the SDV. Since the average Kytril dosage was .7mg, clinics could bill Medicare for four 1mg dosages ***plus*** an extra one or two dosages that could be

obtained from the ***same*** MDV, ***without any need to batch remainders***. Van Thiel acknowledged that, until the Kytril J-Code was later changed, the MDV afforded the same opportunity to physicians for double dipping as the SDV. GSK Ex. 102 (Van Thiel Dep. at 81-82).

SKB's sales force promoted the MDV so as to ensure that the clinics got the message:

* An SKB sales piece entitled "[redacted]" shows that Kytril's spread is better than Zofran's spread due to the double dipping opportunity with the MDV. GSK Ex. 87 (Pinter Ex. 3). This document must have been created prior to the J-Code change because it refers to 1mg as the "[redacted]" Jim Pinter acknowledged that he received this document from someone at SKB. GSK Ex. 97 (Pinter Dep.).

* An SKB sales piece shows a comparison of Kytril and Anzemet spreads for Tyler Hematology Oncology. GSK Ex. 88 (Francovitch Ex. 15). This document shows that the actual volume of the MDV is 4.3ml because of overfill and touts the opportunity for double dipping: "[redacted]" Levonyak acknowledged that this spreadsheet shows that customers could obtain a greater spread if they billed for extra dosages created from the overfill in the MDV. See also GSK Ex. 100 (Levonyak Dep. at 263-66).

* An SKB sales piece entitled "[redacted]" GSK Ex. 89 (Levonyak Exh. 19). This document shows the savings (and therefore greater profit) versus the 1 mg. vial that can be achieved through the MDV by using it to treat more than four patients.

Of course, double dipping depended on the Kytril J-Code and its 1mg billing unit. Glaxo complained to HCFA about the Kytril J-Code and, as a result, HCFA changed the Kytril J-Code to 1626 and the billing unit to 100mcg. Levonyak informed his sales force of the J-Code change and its resulting effect on Kytril reimbursement. GSK Ex. 90 (Levonyak Exh. 12). The J-Code change effectively ended the opportunity for double dipping with respect to Kytril. Panian acknowledged that he was aware that the J-Code change was intended to end the opportunity for double dipping. GSK Ex. 98 (Panian Dep. at 280-81).

Even after the J-Code was changed, SKB continued to promote the MDV based on its profitability for clinics. Although double dipping was no longer possible, clinics would still be able to administer five or six dosages for a price that was based on 4mg (i.e., four times the price of a 1mg SDV). To the extent that SKB continued to promote the MDV in this manner, it continued to distort AWP and negate the assumptions underlying the Medicare reimbursement scheme. HCFA had no means of factoring in the "[redacted]" dosages available through the MDV. The WAC SKB provided to HCFA for the MDV was simply four times the WAC of the SDV; accordingly, the AWP of the MDV was simply four times the AWP of the SDV.

Examples of this continued promotion of the MDV include the following:

* A 5/99 email from Levonyak to his sales force attached a spreadsheet created by sales representative Panian. GSK Ex. 91 (Pinter Ex. 14). Levonyak's email states: "[redacted]" A note by Panian explaining the spreadsheet states: "[redacted]" The spreadsheet shows that a more favorable "[redacted]" could be obtained through the MDV by seeking reimbursement for the overfill. Levonyak acknowledged that this spreadsheet was intended to be manipulated by sales representatives to allow them to compare the spreads of Kytril and its competitors. GSK Ex. 100 (Levonyak Dep. at 275-77). It also was intended to show what that comparison would be if the customer billed for the overfill and demonstrate that the spread would be better if the customer did so. *Id*. at 277-82. Panian also acknowledged that this spreadsheet shows that a clinic could make a greater spread if they billed for the overfill in the MDV than if they did not. GSK Ex. 98 (Panian Dep. at 224-28). He acknowledged that the spreadsheet also was intended to show that billing for the overfill in the MDV allowed Kytril to compete better on spread with Zofran and Anzemet. *Id*. at 229-32.

* [redacted] GSK Ex. 92 (Francovitch Ex. 16).

* [redacted]
GSK Ex. 93 (Pinter Ex. 12).

* [redacted] GSK Ex. 94 (Levonyak Ex. 10).

Through these mechanisms, SKB sales staff marketed to physician customers the profit that could be obtained based on the spread between AWP and acquisition cost. There is no genuine issue that SKB sales staff, with SBK's approval, marketed Kytril based on spread.

4. There is No Genuine Issue of Material Fact that J&J's AWPs Neither Reflected an Average nor Met OIG Guidelines, and that J&J Purposefully Manipulated And Marketed Spreads

a. J&J manipulated spreads

Various J&J witnesses have confirmed that the AWP price for their products is used as a reference for reimbursement. Thus Centocor acknowledges that it has never sold any Remicade at the AWP price, and in fact never sold any Remicade at any price above WAC (which is 30% below AWP). *See* JJ Ex. 32 (Hoffman Dep. at 128-129); JJ Ex. 26 (McHugh Dep. at 129). Julie McHugh also confirmed that all of the discounts offered on Remicade are based on the WAC price, not AWP. JJ Ex. 26 (McHugh Dep. at 311).

The same is true for Procrit. OBI witnesses uniformly concede that no Procrit was sold at AWP or even at the list price. *See, e.g.*, JJ Ex. 3 (Hiriak Dep. at 203 ("[redacted]")); JJ Ex. 5 (Dempsey Dep. at 72 ("[redacted]")). Instead, throughout the Class Period, OBI offered a

variety of discounts and rebates to numerous customer types, including physicians, hospitals, PBMs, wholesalers, retail pharmacies and long-term care providers to stimulate Procrit sales. *See, e.g.*, JJ Ex. 4 (Kling Dep. at 34); JJ Ex. 5 (Dempsey Dep. at 28-29, 109); JJ Ex. 13 (Amick Dep. at 257-58); [redacted] JJ Ex.15 (Robbins Dep. at 239-40). For example, in the early 1990s, OBI offered a 5 percent off-invoice discount to non-dialysis customers. JJ Ex. 15 (Robbins Dep. at 231). Furthermore, throughout the 1990's, OBI field sales representatives periodically circulated promotional flyers to physicians and hospitals offering enhanced discounts to purchasers of an additional 3 percent. *Id*. at 232-36.

In 2001, in response to Amgen's introduction of a competing drug Aranesp, OBI sought to increase the level of rebates and discounts that it offered to its customers. For instance, in early 2001, OBI initiated new physician and hospital rebate agreements with customers. JJ Ex. 4 (Kling Dep. at 34); JJ Ex. 3 (Hiriak Dep. at 325-30). For example, beginning in 2001, physicians were able to purchase Procrit with a 5 percent discount and eligible to receive additional volume requirement rebates. JJ Ex. 4 (Kling Dep. at 168-69). Hospitals and acute-care facilities were eligible for up-front discounts ranging from 5 to 7 percent. JJ Ex. 4 (Kling Dep. at 193); JJ Ex. 3 (Hiriak Dep. at 591 ("[redacted]")). According to James "Dick" Robbins, OBI's National Field Sales Director, these additional rebates were offered to "[redacted]" JJ Ex. 15 (Robbins Dep. at 139).

During 2002, OBI offered the Preferred Purchasing Agreement (PPA) to physicians, Value Opportunity Offer agreements (VOO) to hospitals providing 5 to 7 percent up-front

discounts and 1 percent rebate, a Managed Care and PBM program offering 7 percent rebate provided a 85 percent market share was maintained, and a Physician GPO program providing a 1 percent administrative fee for groups whose market share exceeds the national average.

Even though OBI offered these significant and varying rebates and steep off-invoice discounts throughout the Class Period, OBI never adjusted its AWPs or the method for computing them. In fact, despite providing various rebates and discounts to numerous customer types throughout the 1990s, the AWPs for Procrit were never adjusted downwards to reflect those rebates and discounts, and, in fact, the AWPs of Procrit remained unchanged from 1991 until 1997 when OBI announced the first-ever Procrit price change. Despite the substantial rebates and discounts that OBI offered to customers after Aranesp entered the market, the company never once lowered the AWP of Procrit or the spread between AWP and WAC. Notably, OBI's 30(b)(6) designee, Thomas Hiriak, testified that although OBI always calculated and knew the "net price" for Procrit (net of discounts, chargebacks and rebates), OBI did not share the data with anyone outside the company. JJ Ex. 3 (Hiriak Dep. at 254).

b. J&J marketed spreads

Both Centocor and OBI continuously engaged in conduct to promote the spreads they had created. Throughout the Class period, OBI engaged in a deliberate strategy of marketing the potential profitability of prescribing Procrit. Even prior to bringing Procrit to market, OBI was aware that the amount of reimbursement was a primary driver in the physician, hospital and managed care markets. JJ Ex. 3 (Hiriak Dep. at 92-95). Moreover, by 1993, OBI knew that this was especially true for oncologists, who it knew made a "[redacted]" portion of their revenue from the drugs they prescribed. JJ Ex. 3 (Hiriak Dep. at 96-97).

OBI also internally acknowledged that its Procrit sales were driven by physician profit incentives. Attached to a document dated February 12, 1998 and entitled "[redacted]" Cathleen Dooley, OBI's former Director of Reimbursement, baldly admitted that from the early 1990s until late 1997, the Procrit "[redacted]" JJ Ex. 17 ([redacted]). In the same document, Ms. Dooley also noted that between 1998 and 2002, when the "[redacted]" *Id.* That physicians were purchasing Procrit for profit was further corroborated by several 1999 reports authored by McKinsey and Company for OBI. For example, in the reports, McKinsey concludes that "[redacted]" JJ Ex. 18 ([redacted]). Elsewhere in the same document, McKinsey disclosed that as of June 1999, Procrit had primarily been "[redacted]" JJ Ex. 18 ([redacted]).

During the Class period, OBI testimony indicates that the company took seven price increases between 1997 and 2004. One significant factor that OBI weighed whenever considering taking a price change was the amount of margin available to Procrit customers. OBI's Cathy Dooley, emphasized that the company's pricing strategy must enable physicians to receive an amount of reimbursement from Medicare that made them whole prior to collecting any co-payment revenue from the patient. See JJ Ex. 19 ([redacted]). Furthermore, when asked what factors were weighed when OBI considered taking Procrit price increases, Thomas Hiriak, OBI's Executive Director of Strategic Accounts and 30(b)(6) witness testified:

[redacted]

JJ Ex. 3 (Hiriak Dep. at 229 (emphasis added)). Cathleen Dooley referred to the spread between AWP reimbursement and acquisition cost as a "[redacted]" for physicians. JJ Ex. 20 ([redacted]). One reason why OBI considered raising prices was that the higher price would also increase reimbursements, a move that would be favorably received by physicians. *See* JJ Ex. 21 ([redacted]).

Moreover, sales materials provided to OBI field sales managers and representatives highlighted the financial benefit of the spread to customers. For example, in a document designated "[redacted]" and entitled "[redacted]", OBI outlines the amount of reimbursement and "profits" available to physicians who provide Procrit rather than transfuse patients. JJ Ex. 22 ([redacted]). OBI provided additional training documents to its sales force that contained calculations that physicians who prescribe 40,000 units of Procrit over the normal 18 week course would receive $8,010 of AWP based reimbursement. JJ Ex. 23 ([redacted]). Similarly, documents provided to Sales Force District Managers at a training session for selling to oncology clinics include a heading "[redacted]" JJ Ex. 24 ([redacted]). Therefore, part of the training exercise included demonstrating to the oncologist that each patient that receives Procrit treatment is worth $8,000 in AWP reimbursement.

OBI also developed computer programs that were designed to show to a physician that

she or he would be better off staying with Procrit than switching to Aranesp, Amgen's competing drug, due to the comparative value of the discounts and rebates offered by OBI. JJ Ex. 3 (Hiriak Dep. at 173). Testimony shows that certain CDs shown to physicians refer to AWP reimbursement. JJ Ex. 15 (Robbins Dep. at 292-93); *see also* JJ Ex. 16 ([redacted]). Thus, OBI armed its sales force with information that it knew addressed a key driver for Procrit customers, and enabled the sales force to discuss the economic benefits of prescribing Procrit based on the spread.

In the case of Remicade, marketing the drug's spread as a way to induce physicians to perform in-office infusions was part of Centocor's strategy from before the initial Launch in 1998. See JJ Ex. 28 ([redacted]). Centocor's efforts were mostly in the form of the Practice Management Program ("PMP"), which was designed to allow doctors to calculate the costs and profit of performing in-office infusions of Remicade. *See* JJ Ex. 34 ([redacted]).

Centocor's Office Based Infusion Guide, attached as JJ Ex. 53, states in its Introduction that "[redacted]" (page 4, [redacted]) and refers the physician to the Financial Impact Worksheet for a more detailed calculation of potential profit. That worksheet appears on page 8, [redacted], and allows doctors, with the help of their Centocor sales representatives, to calculate the spread (reimbursement at AWP minus infusion costs) and profit ("[redacted]") from performing Remicade infusions. *See* JJ Ex. 26 (McHugh Dep. at 396-97). Centocor's Practice Management Program is an institutionalized program to market the spread on Remicade.

A detailed explanation of how Centocor actually marketed the spread comes from the deposition of Centocor's Laura Glassco, a National Accounts Manager and Regional Business

Director. Ms. Glassco explained that Centocor conducted numerous "[redacted]" in which Doctors would travel to out-of-town hotels (at Centocor's expense) to hear presentations about Remicade. *See* JJ Ex. 35 (Glassco Dep. at 29-30). At these seminars Ms. Glassco would explain in detail how much physicians could make by buying Remicade, infusing it and then billing for it at prices based on AWP. Ms. Glassco used powerpoint charts to graphically illustrate how much "[redacted]" a physician could make from using the Remicade spread. *See* Glassco powerpoint presentation at JJ Ex. 36 ([redacted]) and JJ Ex. 36 (Glassco Dep. at 105-09, 111-13). Significantly, Ms. Glassco stated that at some point after this litigation was commenced Centocor gave instructions to its employees to stop talking to physicians about profit. JJ Ex. 36 (Glassco Dep. at 113-14).

5. There is No Genuine Issue of Material Fact that Schering-Plough's AWPs Neither Reflected an Average nor Met OIG Guidelines, and that Schering-Plough Purposefully Purposefully Manipulated And Marketed Spreads

Discovery has confirmed that SPW established inflated AWPs with full knowledge that AWP was the benchmark for third party payors' reimbursements to providers. Discovery has also shown that the creation and maintenance of favorable spreads for reimbursement to pharmacies and providers were no accident; such spreads were express objectives of SPW.

Perhaps one of the most telling documents revealing that SPW intentionally "[redacted]" The memo, hereinafter referred to as the "[redacted]" addressed pricing strategies against competitive brands and proposed rebates for retail pharmacies. At the time of the memo, Longstreet was the Director of Managed Care Marketing for the OBBU and was working with

the Trade Team on devising market share rebate offers to pharmacies.[31] Prior to his OBBU position, Longstreet, since joining SPW in 1989, had worked as a sales representative for branded products calling on both independent and chain pharmacies, a market research analyst that considered pharmacy market incentives, a Manager of Contracts and Information, and as Manager of Managed Care and Disease Management working with the Medicaid marketplace and state administered programs.

With his considerable experience within SPW formulating and implementing pricing strategies, [redacted] made the following comments on AWP pricing regarding both branded and generic SPW products:

[redacted]

[31] The Trade Team consisted of Frank Dilascia, SP-VP Trade Sales and Pharmacy Development; Mike Walsh, SP-Trade Sales Director NE; Peter Kamins, SP-Trade Sales Director SE; Joe Caso, VP Key Pharmaceuticals Marketing and Sales; and Bob Bucko, SP-VP Finance. *See* SP Ex. 14.

[redacted]

Attached as SP Ex. 14 ([redacted] (emphasis added).

Longstreet's description of the use of "[redacted]" in gaming the system is a reflection of the general knowledge of and acceptance by SPW executives and sales managers of those tactics. [redacted] SP Ex. 14 ([redacted]).

Another example of the understanding by SPW employees that SPW was involved in a "[redacted]" is the deposition testimony of Louis Manfredi, a business development manager for SPW, 7/11/2005 Dep. W. Va. Case (line 13, page 89 to line 14, page 90):

[redacted]

[Emphasis added. Excerpt is shown in SP Ex. 15.]

The "[redacted]" is a clear admission by a knowledgeable SPW executive of the phony AWP schemes employed by SPW to move the markets for SPW products at inflated prices to the damage of Medicaid, Medicare, state programs, TTPs and consumers, namely: (i)

for generics, create favorable spreads by setting and keeping a high AWP while dropping actual acquisition cost; and (ii) for brands, manipulate AWP and actual acquisition costs to create favorable reimbursement spreads for pharmacies or providers.

SPW's use of AWPs has never been linked to accuracy, and has been meaningful only with regard to marketing the spread for provider reimbursements. SPW admitted in their answers that the reported AWPs are typically higher than the prices ultimately paid for by providers purchasing such medicines from wholesalers and distributors.[32]

More significantly, discovery has confirmed that SPW manipulated AWP pricing by maintaining spreads that benefited providers and retailers at the expense of the class.[33] The favorable spreads for the providers were created by AWP-acquisition price differentials[34] and

[32] These admissions are contained in ¶¶ 3 and 485 of Warrick's and SP's Answers to Intervenor's Amended Master Consolidated Class Action Complaint filed April 9, 2004 (Dkt. No. 777).

[33] *See* "[redacted]". [redacted]; and 8/1/00 sale proposal of Albuterol Inhalant Aerosol with spread of 681% - SPW011448, SP Ex. 18.

[34] *See* SP Ex. 16 ([redacted]) (9/21/95 Warrick price change notice/advertisement to Walgreen Co. for albuterol sulfate solution, 0.5%, 20ml with AWP of $14.99, Direct price of $9.00, less off-invoice instant rebate of 23%, leaving net invoice price of $6.93 (a spread of 116%) less current rebate plus a price protected order to purchase at old price. See also SP Ex. 20, [redacted] (a spread of 275%) plus an offer of off-invoice 10% product rebate on future purchses, to be issue quarterly, plus an offer of off-invoice rebates for combined markets share, Proventil Brand/Warrick Generick, for albuterol products. Added to all of the offered rebates is a Inventory Adjustment incentive whereby Warrick adjusts on-hand inventory in the event of market price decrease.

off-invoice inducements such as discounts,[35] rebates,[36] price-protected orders,[37] free goods,[38] grants,[39] stock/inventory adjustment,[40] and bundling of products with steeply discounted drugs.[41]

The transactional data that reflects the implementation and amounts involved in the inflated pricing of products and the various discounting schemes was produced to plaintiffs in SPW's databases designated Direct Sales ([redacted]), Chargebacks ([redacted]) and Rebates ([redacted]). From this data, the "spreads" (percentage difference between the AWP and the price after factoring rebates and discounts) for each NDC of the subject drugs can be readily calculated as demonstrated in SP Ex. 26.

While the spread chart represented by SP Ex. 26 generally captures the rebates and discounts not reflected in the AWPs, SPW used specific tactics to create spread in marketing the subject drugs of this action, as described more fully below.

a. INTEGRILIN®

Integrilin is prescribed for acute coronary syndrome and utilized during heart catheterization procedures. As with all their drugs, Schering set and published phony AWPs that

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[35] *Id.*)

[36] *Id.* Warrick rebates are described in detail in [redacted], SP Exs. 18 and 19.

[37] *Id.*

[38] While Schering provided off-invoice discounts and free goods to doctors, for a "distinct competitor advantage" with dispensing doctors, Schering "went with free goods whenever possible." Email exchanges between Olav Hellebo and Peter Maguire, March 2001. SP Ex. 20 ([redacted]).

[39] A blatant example of misuse of offering grants for illegal incentives to obtain market share for integrilin is an inter-office memo dated 9/29/2000 reporting on meetings with Catholic Healthcare West wherein the object was to increase utilization of integrilin, SP was willing to negotiate "a commitment of $ for unrestricted educational grants- which we plan to discuss on our next visit per them making INTEGRILIN the preferred agent system wide. SP Ex. 21.

[40] Stock/Inventory adjustments is a retroactive payment/credit to certain classes of trades that result when the price of product occurs within a certain time period after initial purchase. On one occasion, such a rebated netted CVS a $504,097 credit. See SP Ex. 22 (Kapur Dep. at 227 and Dep Ex. 151).

[41]SP records for the year 2002 show bundle Warrick albuterol products with Schering branded products at steeply discounted prices. See SP Ex.14.

were intended to be used in reimbursement scenarios by Medicare, TTPs and, consumers. While generally administered in the hospital setting, on August 1, 2000, HCFA implemented the Medicare Hospital Outpatient Prospective Payment System (OPPS) under the Balanced Budget Refinement Act (BBRA). The BBRA mandated payment for drugs approved for pass-through payment at 95% of AWP. This reimbursement status and how to ensure that protocols and billing would take advantage of Medicare reimbursement was advertised by Schering to all its customers.[42]

The protocol that allowed pass-through payment was referred to by the Schering sales force as "[redacted]". In 2000 for the 2mg, 100ml vial of Integrilin, the Schering AWP and discounting had a marketing advantage over competitors by creating a spread that allowed customers to obtain reimbursement at $200 above acquisition cost for each 2mg, 100ml vial. Documents produced by SPW show that SPW sales representatives were provided promotional outlines on the integrilin reimbursement spread advantage so that they could use the information in their sales pitch to customers.[43]

Schering marketed Integrilin using off-invoice discounts[44] and price protection orders[45] that resulted in inflating the already phony AWP. To increase market share, Schering marketed

[42] See [redacted] SP Ex. 25 ([redacted]). Schering also provided sales force with "[redacted]" for customer marketing that included form letters explaining Integrilin reimbursement, powerpoint slides and schedules of reimbursement teleconferences to help sell integrilin on the basis of the reimbursement set at 95% of AWP. SP Ex. 26 ([redacted]).

[43] See SP Ex. 27 ([redacted]).

[44] In a 2001 Q&A for a multi-company collaboration, Schering noted in an "INTERNAL USE" comment that net price increases were dependant on contracted discounting. SP Ex.281 ([redacted]). For specific rebates of 7% and 4.5% for Integrilin. SP Ex. 29 ([redacted]). Also see Schering Integrilin Committed Member Program form ([redacted]) utilized for promoting off-invoice discounts for market share performance, SP Ex. 30.

[45] PPOs were extensively used to create spread and move the market. See SP Ex. 31 ([redacted]).

Integrilin by showing to customers the profitability of Integrilin in presentations that would show "[redacted]" when using "[redacted]" and 95% of phony "[redacted]"[46]

The transactional databases capture the reported discounts and rebates for the class period for Integrilin and is solid evidence of the creation and amount of "[redacted]" and damages.[47] Actual spreads for Integrilin calculated from the transactional data that captured reported discounts and rebates range between 18.6% and 70.4%.[48]

b. Temodar®

Temodar received FDA approval on Aug 11, 1999 for treatment of adult patients with refractory anaplastic astrocytoma.[49] The fact that Medicare provided coverage under Part-B for this self-administered oncology drug was important to the marketing of Temodar by the SPW sales force. All oncology drugs sales representative were trained to provide reimbursement information to the physicians and pharmacies that they called on. Depositions of SPW sales representatives confirmed that it was there standard practice to make reimbursement information a part of their sales pitch to their customers.[50]

Temodar rebates, actual and estimated/planned, for the years 1998 through 2003 are set forth in [redacted] (rebates between 3-5.7%). Actual spreads from the transactional databases show Temodar spreads for the Temodar products to range from 19.8% to 55.1% for the class period.[51]

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[46] *See* SP Ex. 32 ([redacted]).

[47] *See* SP Ex. 26.

[48] *See* SP Ex. 26.

[49] *See* SP Ex. 33 (Memo with press release, [redacted]).

[50] SP Ex. 37 (Excerpts from SPW drug representatives' depositions).

[51] *See* SP Ex. 27.

c. Intron-A®

Marketing of profitability to physicians of Intron-A treating bladder cancer based on the difference of AWP/NDP and Medicare reimbursement (95% of AWP) is demonstrated by a 1998 Memo to Oncology sales representatives with profit message for urologists and oncologists for a new 95% of AWP reimbursement for using Intron A for bladder Cancer. The message was "[redacted]". [redacted][52]

The reported off-invoice discounts[53] and rebates are captured within the transactional databases produced to plaintiffs. The spread chart (Power Point Slide No. 67) demonstrates spreads for Intron A between 20.5% and 141.9% for the subject time period.

d. Proventil®

The SPW albuterol sulfate line of products carry two separate labels, Schering Proventil® and Warrick Albuterol. The products are identical, manufactured under the same NDA, but with different NDCs

At the outset of the class period in 1991, Proventil still enjoyed the price protection under patent and the AWP/actual sales price spread generally reflected the standard AWP mark-up of 20%. However, in anticipation of generic competition in 1992 and the launch of albuterol

[52] SP Ex. 35 ([redacted]) is an outline showing Intron A utilization profitability showing a spread of ~14% between net direct price and reimbursed amount. Excluded from this outline are additional contracted discounts and price protection order discounts that would increase the spread.

[53] Schering had a standard form marketing Intron-A only by offering an off-invoice discount of 14% off NDP (~30% off AWP) if quarterly utilization rate met or exceeded quarterly national market share benchmark reported by NDC. *See* SP Ex. 36 ([redacted]).

generics in 1993, Schering increased the spread in order to compete against other manufacturers. In the years that followed, Proventil spreads increased significantly with the highest spread in 2004Q1 of 1279.6%.[54]

Discovery has also shown that actual spreads for Proventil were hidden by bundling discounted/nominal priced Warrick solution to make up value differences or by having discounts/rebates on Proventil sales paid by Warrick through the Schering Brand/Warrick Generic Market Share Programs.[55]

e. Warrick Albuterol Sulfate

Warrick albuterol inhalation products covered under the Medicare DME provisions represent the most serious example of deceptive marketing practices and gaming the system through AWP fixing and price manipulation to move the market. The annual spreads of reported/captured discounts and rebates is evidenced by the AWP/pricing spreads reflected in analysis of the transactional data that shows spreads ranging from 107.4% to 1535.4%[56] The evidence suggests that the spread percentages are higher than reflected in the transactional data as many rebates, such as administrative fee rebates, new product launch rebates, certain customer chargeback rebates, and certain auto-substitution contract sales rebates were not captured in the databases provided by SPW.[57]

[54] *See* SP Ex. 26.

[55] *See* SP Ex. 37 ([redacted]).

[56] *See* SP Ex. 26.

[57] *See* SP Ex. 38 [redacted]

Finally, as a result of this and similar litigation, SWP, in communicating pricing information to governmental drug programs, now includes the following concessions that confirm plaintiffs' position in this motion for partial summary judgment:

[redacted][58]

IV. LEGAL ARGUMENT: EACH TRACK 1 DEFENDANT HAS COMMITTED UNFAIR AND DECEPTIVE ACTS OR PRACTICES AS A MATTER OF LAW

Massachusetts Gen. Laws Ch. 93A, § 2 prohibits "[u]nfair or deceptive acts or practices in the conduct of any trade or commerce." Chapter 93A "is a statute of broad impact" passed "to aid consumers and others . . . by making conduct unlawful which was not unlawful under the common law or any prior statute." *Slaney v. Westwood Auto, Inc.*, 366 Mass. 688, 693, 322 N.E.2d 768 (1975) (quoting *Commonwealth v. DeCotis*, 366 Mass. 234, 244 n.8 (1974)). In particular, the definition of an actionable unfair or deceptive act or practice "goes far beyond the scope of the common law action for fraud and deceit." *Id.* at 703. "[T]echnicalities are not to be read into the statute in such a way as to impede the accomplishment of substantial justice." *Leardi v. Brown*, 394 Mass. 151, 159, 474 N.E.2d 1094 (1985) (quoting *Baldassari v. Public Fin. Trust*, 369 Mass. 33, 41 (1975)).

[58] *See* SP Ex. 40 ([redacted]) (April 9, 2003 Letter from Schering to Connecticut Commission of Pharmacy regarding Schering Corporation Pricing as of March 31, 2003).

Properly applying Chapter 93A jurisprudence here demonstrates that the course of conduct outlined above for each Track 1 Defendant is both unfair and deceptive as a matter of law.[59]

A. Each Track 1 Defendant Has Committed Unfair Acts And Practices In Violation Of G.L. Ch. 93A

An unfair act or practice is not amenable to a bounded definition because, as courts have recognized, "[i]t is impossible to frame definitions which embrace all unfair practices. There is no limit to human inventiveness in this field." *Levings v. Forbes & Wallace, Inc.*, 8 Mass. App. Ct. 498, 503, 396 N.E.2d 149 (1979) (quoting H. R. Conf. Rep. No. 1142, 63d Cong., 2d Sess. (1914)). Nonetheless, Massachusetts courts, following federal jurisprudence under the Federal Trade Commission Act,[60] have employed the following factors in evaluating whether conduct is unfair: (i) whether the practice is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (ii) whether it is immoral, unethical, oppressive or unscrupulous; and (iii) whether it causes substantial injury to consumers, competitors or other business people. *PMP Assocs., Inc. v. Globe Newspaper Co.*, 366 Mass. 593, 596, 321 N.E.2d 915 (1975) (citing *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972)).

"Whether a given practice runs afoul of these touchstones must be determined from the circumstances of each case." *Levings*, 8 Mass. App. Ct. at 504, 396 N.E.2d 149. In doing so, courts evaluate the "equities between the parties," and "[w]hat a defendant knew or should have known may be relevant" in making that determination. *Swanson v. Bankers Life Co.*, 389 Mass.

[59] Although Defendants' conduct is both unfair and deceptive, the Court need not find the presence of both in order to find that Defendants violated G.L. Ch. 93A. For example, a practice can be unfair without being deceptive. *See, e.g., Service Publications, Inc. v. Goverman*, 396 Mass. 567, 578, 487 N.E.2d 520 (1986).

[60] Courts are to be guided by interpretations given by the Federal Trade Commission and federal courts to section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1). *Slaney*, 366 Mass. at 694, 322 N.E.2d 768.

345, 349, 450 N.E.2d 577 (1983). The Court is to "focus on the nature of challenged conduct and on the purpose and effect of that conduct as the crucial factors in making a G. L. c. 93A fairness determination." *Massachusetts Employers Ins. Exch. v. Propac-Mass, Inc.*, 420 Mass. 39, 43, 648 N.E.2d 435 (1995).

Defendants' acts and practices are unfair acts as a matter of law. First, Defendants perpetuated the publication of inflated AWPs while knowing full well that those same AWPs constitute the Medicare Part B reimbursement benchmark, manipulated spreads between AWPs and actual costs, and took concrete steps to market those spreads to providers. Each of these actions readily falls within the penumbra of common-law, statutory, or other established concept of unfairness, particularly given the OIG's admonitions that: (i) AWP must be a meaningful figure that is not artificially inflated; (ii) the "government sets reimbursement with the expectation that the data provided are complete and accurate" and include various price reductions; and (iii) it is illegal for a manufacturer to knowingly establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

Second, that same conduct is immoral, unethical, oppressive or unscrupulous. It rises to a "level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce." *Levings*, 8 Mass. App. Ct. at 504, 396 N.E.2d 149. Or, as another court has waxed, it leaves a "rancid flavor of unfairness." *Propac-Mass, Inc.*, 420 Mass. at 43, 648 N.E.2d 435 (quoting *Atkinson v. Rosenthal*, 33 Mass. App. Ct. 219, 226, 598 N.E.2d 666 (1992)). And although they perpetrated such conduct, even the Track 1 Defendants recognized that manipulating and marketing spreads was unethical or wrong. *See, e.g.*, Schultz Dep. II at 93-95, 124-29 (AstraZeneca Pricing Strategy Manager, Erik Schultz, explained that he thought it

was "sleazy" and "an ethical problem" for AstraZeneca to evaluate and increase the AWPs for Zoladex based on whether physicians were making enough profit); Levonyak Dep. at 80-81, 91-93, 214-18 (Kytril Sales Director explaining how SKB sales force discussed spread issues with customers, then were prohibited from doing so, and then were authorized to discuss in a nuanced manner); BMS Ex. 49, Jan. 26, 2001, BMS/AWP/000192876 (BMS Memo acknowledging that "the spread should not be used as a promotional or marketing tool"); JJ Ex. 35 (Glassco Dep. at 113-14 (Centocor's National Accounts Manager and Regional Business Director instructing employees to stop talking to physicians about profit)). There should be no debate that gouging elderly Medicare Part B beneficiaries is immoral, unethical, oppressive and unscrupulous, especially when the most vulnerable among them – seniors going through traumatic cancer treatments – are adversely affected.

Third, as the Court has already recognized, Medicare Part B beneficiaries and Medi-Gap insurers pay 20 percent of the allowed amount for covered drugs. *In re AWP*, 230 F.R.D. at 71. Thus, it is axiomatic that Defendants have caused substantial injury to the consumer and insurer members of Classes 1 and 2.

All of the unfairness factors apply here. Plaintiffs are entitled to summary judgment on this issue in favor of Classes 1 and 2.

B. Each Track 1 Defendant Has Committed <u>Deceptive</u> Acts And Practices In Violation Of G.L. Ch. 93A

An act or practice is deceptive if it possesses a tendency to deceive. *Leardi v. Brown*, 394 Mass. at 156, 474 N.E.2d 1094. *See also* 940 C.M.R. 3.04 ("No claim or representation shall be made by any means which has the capacity or tendency or effect of deceiving buyers or prospective buyers as to the value or the past, present, common or usual price of a product, or as

to any reduction in price of a product, or any saving relating to a product."); 940 C.M.R. 3.05(1) ("No claim or representation shall be made by any means concerning a product which directly, or by implication, or by failure to adequately disclose additional relevant information, has the capacity or tendency or effect of deceiving buyers or prospective buyers in any material respect.").[61]

"In determining whether an act or practice is deceptive, 'regard must be had, not to fine spun distinctions and arguments that may be made in excuse, but to the effect which it might reasonably be expected to have upon the general public.'" *Leardi*, 394 Mass. at 156, 474 N.E.2d 1094 (quoting *P. Lorillard Co. v. FTC*, 186 F.2d 52, 58 (4th Cir. 1950)). The plaintiff need not prove that the defendant intended to deceive the plaintiff. *Aspinall v. Philip Morris Cos., Inc.*, 442 Mass. 381, 394, 813 N.E.2d 476 (2004). Nor is proof of reliance required as long as there is a causal relationship between the act or practice and injury to the plaintiff. *Fraser Eng'g Co., Inc. v. Desmond*, 26 Mass. App. Ct. 99, 104, 524 N.E. 2d 110 (1988).

Defendants' course of conduct was deceptive as a matter of law, as the tendency or capacity to deceive is plainly present. Defendants' deliberate decision to report AWPs to national pharmaceutical industry publications or list prices with knowledge of how they would be marked up to result in AWPs – ***knowing that these published AWPs would form the basis of an industry-wide reimbursement system*** – obligated Defendants by law to ensure that these pricing benchmarks were ***not*** misleading. For example, it is axiomatic under statutes prohibiting misrepresentations that "a party who discloses partial information that may be misleading has a duty to reveal all the material facts he knows to avoid deceiving the other party." *V.H.S. Realty,*

[61] These Attorney General regulations have the force of law, and violations of them constitute violations of G.L. ch. 93A. *Purity Supreme, Inc. v. Attorney Gen.*, 380 Mass. 762, 775, 407 N.E.2d 297 (1980).

Inc. v. Texaco, Inc., 757 F.2d 411, 414 (1st Cir. 1985); *see also Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 26 (1st Cir. 1987) (RICO and securities claims). Indeed, the First Circuit has specifically held that "[w]hen a corporation does make a disclosure – ***whether it be voluntary or required*** – there is a duty to make it complete and accurate." *Roeder*, 814 F.2d at 26 (emphasis added). "'Fragmentary information may be as misleading . . . as active misrepresentation, and half-truths may be as actionable as whole lies . . . ." *V.H.S. Realty,* 757 F.2d at 414-15 (quoting *Kannavos v. Annino*, 356 Mass. 42, 48, 247 N.E.2d 708 (1969)). Thus, if a drug manufacturer "chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole truth." *Roeder*, 814 F.2d at 26 (quoting *Grossman v. Waste Mgmt., Inc*., 589 F. Supp. 395, 409 (N.D. Ill. 1984)).[62]

Moreoever, as the evidence demonstrates, each Track 1 Defendant enacted a concerted scheme to manipulate spreads on their Subject Drugs and then market those spreads. "[T]he effect [that this] might reasonably be expected to have upon the general public," *Leardi*, 394 Mass. at 156, 474 N.E.2d 1094, is obvious: millions of Medicare Part B beneficiaries have become obligated to make inflated co-payments for Subject Drugs as a direct and proximate result of the Track 1 Defendants' AWP manipulation, ***and at no fault of their own***. Plaintiffs and members of Class 1 and Class 2 were victimized by the simple action of making co-pays pursuant to a statutory directive and had no control over the amounts of those co-pays. This highlights the insidiousness of Defendants' actions and weighs heavily in favor of finding as a

[62] *See also Turner v. Johnson & Johnson*, 809 F.2d 90, 100 (1st Cir. 1986) (finding that "an incomplete or partial statement may be the basis for fraud when only full disclosure would avoid deception"); *Augat, Inc. v. Collier*, 1996 U.S. Dist. Lexis 2702, at *47 (D. Mass. Jan. 22, 1996) (noting that disclosure of partial information may be fraudulent); *Union Pac. Res. Group, Inc. v. Rhone-Poulenc, Inc.*, 247 F.3d 574, 586 (5th Cir. 2001) (finding disclosure of "some but less than all material facts" may be actionable where "partial disclosure convey[s] a false impression.").

matter of law that Defendants' acts and practices had the capacity to deceive. Plaintiffs are entitled to summary judgment on this issue in favor of Classes 1 and 2.

V. CONCLUSION

For the foregoing reasons, partial summary judgment should be granted against all five Track 1 Defendants on the issues identified above.

DATED: March 15, 2006.

By **/s/ Steve W. Berman**

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on March 15, 2006, I caused copies of **PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
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